FLEXDOSING.com

Bridges the Dosing Gap for Gabapentin Treatment

Relgaabi
(gabapentin) Capsules 200 mg

NDC: 58657-231-01

ADVERSE REACTIONS:
Most common adverse reactions (incidence ≥8% and at least twice that for placebo) were:

- Postherpetic neuralgia: Dizziness, somnolence, and peripheral edema
- Epilepsy in patients >12 years of age: Somnolence, dizziness, ataxia, fatigue, and nystagmus
- Epilepsy in patients 3 to 12 years of age: Viral infection, fever, nausea and/or vomiting, somnolence, and hostility

INDICATIONS:
RELGAABI is indicated for:

- Management of postherpetic neuralgia in adults
- Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy

WARNINGS & PRECAUTIONS:

- Drug Reaction with Eosinophilia and Systemic Symptoms (Multiorgan hypersensitivity): Discontinue if alternative etiology is not established
- Anaphylaxis and Angioedema: Discontinue and evaluate patient immediately
- Driving Impairment; Somnolence/Sedation and Dizziness: Warn patients not to drive until they have gained sufficient experience to assess whether their ability to drive or operate heavy machinery will be impaired
- Suicidal Behavior and Ideation: Monitor for suicidal thoughts/behavior
- Abrupt or rapid discontinuation may increase the risk for seizures. Withdrawal symptoms, or suicidal behavior and ideation have been observed after discontinuation
- Respiratory Depression: May occur with RELGAABI when used with concomitant central nervous system (CNS) depressants, including opioids, or in the setting of underlying respiratory impairment. Monitor patients and adjust dosage as appropriate
- Neuropsychiatric Adverse Reactions in Children 3 to 12 Years of Age: Monitor for such events

For full Prescribing Information, see attached Product Insert.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088.

A Flexible Dosing Option For Gabapentin Treatment

Dose Titration
Stepping up or down between standard doses

Renal Impairment
Slower doses are required based on creatinine clearance

Pediatric Dosing
Weight-based dosing may call for smaller increments

HOW TO WRITE:

Relgaabi

Take 1 capsule by mouth up to three times daily.

☐ 200 mg

Dispense as written.

Visit our website at:
FLEXDOSING.COM

LB-FD-02 Rev. 05/2026

RELGAABI- gabapentin capsule
Method Pharmaceuticals, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use RELGAABI safely and effectively. See full prescribing information for RELGAABI.

RELGAABI (gabapentin) capsules, for oral use
Initial U.S. Approval: 1993

RECENT MAJOR CHANGES

Warnings and Precautions (5.5, 5.6)	4/2025
Warnings and Precautions, removal-Sudden and Unexplained Death in Patients with Epilepsy (5.10)	4/2025

INDICATIONS AND USAGE

RELGAABI is indicated for:

- Postherpetic neuralgia in adults (1)
- Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (1)

DOSAGE AND ADMINISTRATION

- Postherpetic Neuralgia (2.1)
  - Dose can be titrated up as needed to a dose of 1800 mg/day
  - Day 1: Single 300 mg dose
  - Day 2: 600 mg/day (i.e., 300 mg two times a day)
  - Day 3: 900 mg/day (i.e., 300 mg three times a day)

- Epilepsy with Partial Onset Seizures (2.2)
  - Patients 12 years of age and older: starting dose is 300 mg three times daily; may be titrated up to 600 mg three times daily
  - Patients 3 to 11 years of age: starting dose range is 10 to 15 mg/kg/day, given in three divided doses; recommended dose in patients 3 to 4 years of age is 40 mg/kg/day, given in three divided doses; the recommended dose in patients 5 to 11 years of age is 25 to 35 mg/kg/day, given in three divided doses. The recommended dose is reached by upward titration over a period of approximately 3 days

- Dose should be adjusted in patients with reduced renal function (2.3, 2.4)

DOSAGE FORMS AND STRENGTHS

Capsules: 100 mg, 200 mg, 300 mg, and 400 mg (3)

CONTRAINDICATIONS

Known hypersensitivity to RELGAABI or its ingredients (4)

WARNINGS AND PRECAUTIONS

- Drug Reaction with Eosinophilia and Systemic Symptoms (Multiorgan hypersensitivity): Discontinue if alternative etiology is not established (5.1)
- Anaphylaxis and Angioedema: Discontinue and evaluate patient immediately (5.2)
- Driving Impairment; Somnolence/Sedation and Dizziness: Warn patients not to drive until they have gained sufficient experience to assess whether their ability to drive or operate heavy machinery will be impaired (5.3, 5.4)
- Suicidal Behavior and Ideation: Monitor for suicidal thoughts/behavior (5.5)
- Abrupt or rapid discontinuation may increase the risk for seizures. Withdrawal symptoms, or suicidal behavior and ideation have been observed after discontinuation (5.6)
- Respiratory Depression: May occur with RELGAABI when used with concomitant central nervous system (CNS) depressants, including opioids, or in the setting of underlying respiratory impairment. Monitor patients and adjust dosage as appropriate (5.8)
- Neuropsychiatric Adverse Reactions in Children 3 to 12 Years of Age: Monitor for such events (5.9)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥8% and at least twice that for placebo) were:

- Postherpetic neuralgia: Dizziness, somnolence, and peripheral edema (6.1)
- Epilepsy in patients >12 years of age: Somnolence, dizziness, ataxia, fatigue, and nystagmus (6.1)
- Epilepsy in patients 3 to 12 years of age: Viral infection, fever, nausea and/or vomiting, somnolence, and hostility (6.1)

To report SUSPECTED ADVERSE REACTIONS, Method Pharmaceuticals, Inc. at 1-877-250-3427 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Concentrations increased by morphine; may need dose adjustment (5.4, 7.1)

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause fetal harm (8.1)
See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 3/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

RELGAABI is indicated for:

- Management of postherpetic neuralgia in adults
- Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy

2 DOSAGE AND ADMINISTRATION

2.1 Dosage for Postherpetic Neuralgia

In adults with postherpetic neuralgia, RELGAABI may be initiated on Day 1 as a single 300 mg dose, on Day 2 as 600 mg/day (300 mg two times a day), and on Day 3 as 900 mg/day (300 mg three times a day). The dose can subsequently be titrated up as needed for pain relief to a dose of 1800 mg/day (600 mg three times a day). In clinical studies, efficacy was demonstrated over a range of doses from 1800 mg/day to 3600 mg/day with comparable effects across the dose range; however, in these clinical studies, the additional benefit of using doses greater than 1800 mg/day was not demonstrated. Sections or subsections omitted from the full prescribing information are not listed.

2.2 Dosage for Epilepsy with Partial Onset Seizures

Patients 12 Years of Age and Above

The starting dose is 300 mg three times a day. The recommended maintenance dose of RELGAABI is 300 mg to 600 mg three times a day. Dosages up to 2,400 mg/day have been administered in long-term clinical studies. Doses of 3,600 mg/day have also been administered to a small number of patients for a relatively short duration. Administer RELGAABI three times a day using 300 mg or 400 mg capsules. The maximum time between doses should not exceed 12 hours.

Pediatric Patients Age 3 to 11 Years

The starting dose range is 10 mg/kg/day to 15 mg/kg/day, given in three divided doses, and the recommended maintenance dose reached by upward titration over a period of approximately 3 days. The recommended maintenance dose of RELGAABI in patients 3 to 4 years of age is 40 mg/kg/day, given in three divided doses. The recommended maintenance dose of RELGAABI in patients 5 to 11 years of age is 25 mg/kg/day to 35 mg/kg/day, given in three divided doses. RELGAABI may be administered as capsule, or tablet, or using combinations of these formulations. Dosages up to 50 mg/kg/day have been administered in a long-term clinical study. The maximum time interval between doses should not exceed 12 hours.

2.3 Dosage Adjustment in Patients with Renal Impairment

Dosage adjustment in patients 12 years of age and older with renal impairment or undergoing hemodialysis is recommended, as follows (see dosing recommendations above for effective doses in each indication):

TABLE 1. RELGAABI Dosage Based on Renal Function

Renal Function Creatinine Clearance (mL/min)	Total Daily Dose Range (mg/day)	Dose Regimen (mg)				
≥ 60	900 to 3,600	300 TID	400 TID	600 TID	800 TID	1,200 TID
> 30 to 59	400 to 1,400	200 BID	300 BID	400 BID	500 BID	700 BID
> 15 to 29	200 to 700	200 QD	300 QD	400 QD	500 QD	700 QD
15 [a]	100 to 300	100 QD	125 QD	150 QD	200 QD	300 QD
		Post-Hemodialysis Supplemental Dose (mg) [b]				
Hemodialysis		125 [b]	150 [b]	200 [b]	250 [b]	350 [b]

TID = Three times a day; BID = Two times a day; QD = Single daily dose

[a]For patients with creatinine clearance <15 mL/min, reduce daily dose in proportion to creatinine clearance (e.g., patients with a creatinine clearance of 7.5 mL/min should receive one-half the daily dose that patients with a creatinine clearance of 15 mL/min receive).

[b]Patients on hemodialysis should receive maintenance doses based on estimates of creatinine clearance as indicated in the upper portion of the table and a supplemental post-hemodialysis dose administered after each 4 hours of hemodialysis as indicated in the lower portion of the table.

Creatinine clearance (CLCr) is difficult to measure in outpatients. In patients with stable renal function, creatinine clearance can be reasonably well estimated using the equation of Cockcroft and Gault:

$$\text{CLCr} = \frac{[140 - \text{age (years)} \times \text{weight (kg)}}{72 \times \text{serum creatine (mg/dL)}} \quad (\times 0.85 \text{ for female patients})$$

The use of RELGAABI in patients less than 12 years of age with compromised renal function has not been studied.

2.4 Dosage in Elderly

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and

dose should be adjusted based on creatinine clearance values in these patients.

2.5 Administration Information
Administer RELGAABI orally with or without food. RELGAABI capsules should be swallowed whole with water.

If the RELGAABI dose is reduced, discontinued, or substituted with an alternative medication, this should be done gradually over a minimum of 1 week (a longer period may be needed at the discretion of the prescriber).

3 DOSAGE FORMS AND STRENGTHS
Capsules:
- 100 mg: White to off-white powder filled in size "3" hard gelatin capsules with opaque white colored cap and opaque white colored body imprinted SG on cap and 179 on body with black ink.
- 200 mg: White to off-white powder filled in size "2" hard gelatin capsules with opaque light yellow colored cap and opaque white colored body imprinted SG on cap and 607 on body with black ink.
- 300 mg: White to off-white powder filled in size "1" hard gelatin capsules with opaque yellow colored cap and opaque yellow colored body imprinted SG on cap and 180 on body with black ink.
- 400 mg: White to off-white powder filled in size "0" hard gelatin capsules with opaque orange colored cap and opaque orange colored body imprinted SG on cap and 181 on body with black ink.

4 CONTRAINDICATIONS
RELGAABI is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

5 WARNINGS AND PRECAUTIONS
5.1 Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity
Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has occurred with RELGAABI. Some of these reactions have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis sometimes resembling an acute viral infection. Eosinophilia is often present. This disorder is variable in its expression, and other organ systems not noted here may be involved.

It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. RELGAABI should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

5.2 Anaphylaxis and Angioedema
RELGAABI can cause anaphylaxis and angioedema after the first dose or at any time during treatment. Signs and symptoms in reported cases have included difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment. Patients should be instructed to discontinue RELGAABI and seek immediate medical care should they experience signs or symptoms of anaphylaxis or angioedema.

5.3 Effects on Driving and Operating Heavy Machinery
Patients taking RELGAABI should not drive until they have gained sufficient experience to assess whether RELGAABI impairs their ability to drive. Driving performance studies conducted with a prodrug of gabapentin (gabapentin enacarbil tablet, extended-release) indicate that gabapentin may cause significant driving impairment. Prescribers and patients should be aware that patients' ability to assess their own driving competence, as well as their ability to assess the degree of somnolence caused by RELGAABI, can be imperfect. The duration of driving impairment after starting therapy with RELGAABI is unknown. Whether the impairment is related to somnolence [see Warnings and Precautions (5.4)] or other effects of RELGAABI is unknown.

Moreover, because RELGAABI causes somnolence and dizziness [see Warnings and Precautions (5.4)] , patients should be advised not to operate complex machinery until they have gained sufficient experience on RELGAABI to assess whether RELGAABI impairs their ability to perform such tasks.

5.4 Somnolence/Sedation and Dizziness
During the controlled epilepsy trials in patients older than 12 years of age receiving doses of RELGAABI up to 1,800 mg daily, somnolence, dizziness, and ataxia were reported at a greater rate in patients receiving RELGAABI compared to placebo: i.e., 19% in drug versus 9% in placebo for somnolence, 17% in drug versus 7% in placebo for dizziness, and 13% in drug versus 6% in placebo for ataxia. In these trials somnolence, ataxia and fatigue were common adverse reactions leading to discontinuation of RELGAABI in patients older than 12 years of age, with 1.2%, 0.8% and 0.6% discontinuing for these events, respectively.

During the controlled trials in patients with post-herpetic neuralgia, somnolence, and dizziness were reported at a greater rate compared to placebo in patients receiving RELGAABI, in dosages up to 3600 mg per day: i.e., 21% in RELGAABI-treated patients versus 5% in placebo-treated patients for somnolence and 28% in RELGAABI-treated patients versus 8% in placebo-treated patients for dizziness. Dizziness and somnolence were among the most common adverse reactions leading to discontinuation of RELGAABI.

Patients should be carefully observed for signs of central nervous system (CNS) depression, such as somnolence and sedation, when RELGAABI is used with other drugs with sedative properties because of potential synergy. In addition, patients who require concomitant treatment with morphine may experience increases in gabapentin concentrations and may require dose adjustment [see Drug Interactions (7.1)].

5.5 Suicidal Behavior and Ideation
Antiepileptic drugs (AEDs), including RELGAABI, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Suicidal behavior and ideation have also been reported in patients after discontinuation of RELGAABI [see Warnings and Precautions (5.6)] . Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal

thoughts or behavior, and/or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebotreated patients, but the number is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5 years to 100 years) in the clinical trials analyzed. Table 2 shows absolute and relative risk by indication for all evaluated AEDs.

Table 2 Risk by Indication for Antiepileptic Drugs in Pooled Analysis

Indication	Placebo Patients with Events Per 1,000 Patients	Drug Patients with Events Per 1,000 Patients	Relative Risk:Incidence of Events in Drug Patients/Incidence in Placebo Patients	Risk Difference: Additional Drug Patients with Events Per 1,000 Patients
Epilepsy	1.0	3.4	3.5	2.4
Psychiatric	5.7	8.5	1.5	2.9
Other	1.0	1.8	1.9	0.9
Total	2.4	4.3	1.8	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.

Anyone considering prescribing RELGAABI or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Patients, their caregivers, and families should be informed that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

5.6 Increased Risk of Seizures and Other Adverse Reactions with Abrupt or Rapid Discontinuation

Antiepileptic drugs should not be abruptly discontinued because of the possibility of increasing seizure frequency.

When RELGAABI is being discontinued, the dose should be tapered over at least a oneweek period.

After discontinuation of short-term and long-term treatment with gabapentin, withdrawal symptoms have been observed in some patients [see Adverse Reactions (6.2)and Drug Abuse and Dependence (9.3)]. Suicidal behavior and ideation have also been reported in patients after discontinuation of RELGAABI [see Warnings and Precautions (5.5)].

5.7 Status Epilepticus

In the placebo-controlled epilepsy studies in patients >12 years of age, the incidence of status epilepticus in patients receiving RELGAABI was 0.6% (3 of 543) versus 0.5% in patients receiving placebo (2 of 378). Among the 2074 patients >12 years of age treated with RELGAABI across all epilepsy studies (controlled and uncontrolled), 31 (1.5%) had status epilepticus. Of these, 14 patients had no prior history of status epilepticus either before treatment or while on other medications. Because adequate historical data are not available, it is impossible to say whether or not treatment with RELGAABI is associated with a higher or lower rate of status epilepticus than would be expected to occur in a similar population not treated with RELGAABI.

5.8 Respiratory Depression

There is evidence from case reports, human studies, and animal studies associating gabapentin with serious, life-threatening, or fatal respiratory depression when coadministered with CNS depressants, including opioids, or in the setting of underlying respiratory impairment. When the decision is made to co-prescribe RELGAABI with another CNS depressant, particularly an opioid, or to prescribe RELGAABI to patients with underlying respiratory impairment, monitor patients for symptoms of respiratory depression and sedation, and consider initiating RELGAABI at a low dose. The management of respiratory depression may include close observation, supportive measures, and reduction or withdrawal of CNS depressants (including RELGAABI).

5.9 Neuropsychiatric Adverse Reactions (Pediatric Patients 3 to 12 Years of Age)

Gabapentin use in pediatric patients with epilepsy 3 to 12 years of age is associated with the occurrence of CNS related adverse reactions. The most significant of these can be classified into the following categories: 1) emotional lability (primarily behavioral problems), 2) hostility, including aggressive behaviors, 3) thought disorder, including concentration problems and change in school performance, and 4) hyperkinesia (primarily restlessness and hyperactivity). Among the gabapentin-treated patients, most of the reactions were mild to moderate in intensity.

In controlled clinical epilepsy trials in pediatric patients 3 to 12 years of age, the incidence of these adverse reactions was: emotional lability 6% (gabapentin-treated patients) versus 1.3% (placebo-treated patients); hostility 5.2% versus 1.3%; hyperkinesia 4.7% versus 2.9%; and thought disorder 1.7% versus 0%. One of these reactions, a report of hostility, was

considered serious. Discontinuation of gabapentin treatment occurred in 1.3% of patients reporting emotional lability and hyperkinesia and 0.9% of gabapentin treated patients reporting hostility and thought disorder. One placebo-treated patient (0.4%) withdrew due to emotional lability.

5.10 Tumorigenic Potential

In an oral carcinogenicity study, gabapentin increased the incidence of pancreatic acinar cell tumors in rats [see Nonclinical Toxicology (13.1)]. The clinical significance of this finding is unknown. Clinical experience during gabapentin's premarketing development provides no direct means to assess its potential for inducing tumors in humans. development provides no direct means to assess its potential for inducing tumors in humans.

In clinical studies in adjunctive therapy in epilepsy comprising 2,085 patient-years of exposure in patients >12 years of age, new tumors were reported in 10 patients (2 breast, 3 brain, 2 lung, 1 adrenal, 1 non-Hodgkin's lymphoma, 1 endometrial carcinoma in situ), and preexisting tumors worsened in 11 patients (9 brain, 1 breast, 1 prostate) during or up to 2 years following discontinuation of RELGAABI. Without knowledge of the background incidence and recurrence in a similar population not treated with RELGAABI, it is impossible to know whether the incidence seen in this cohort is or is not affected by treatment.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections:

- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan
- Hypersensitivity [see Warnings and Precautions (5.1)]
- Anaphylaxis and Angioedema [see Warnings and Precautions (5.2)]
- Somnolence/Sedation and Dizziness [see Warnings and Precautions (5.4)]
- Suicidal Behavior and Ideation [see Warnings and Precautions (5.5)]
- Increased Risk of Seizures and Other Adverse Reactions with Abrupt or Rapid
- Discontinuation [see Warnings and Precautions (5.6)]
- Status Epilepticus [see Warnings and Precautions (5.7)]
- Respiratory Depression [see Warnings and Precautions (5.8)]
- Neuropsychiatric Adverse Reactions (Pediatric Patients 3 to 12 Years of Age) [see Warnings and Precautions (5.9)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Postherpetic Neuralgia

The most common adverse reactions associated with the use of RELGAABI in adults, not seen at an equivalent frequency among placebo-treated patients, were dizziness, somnolence, and peripheral edema.

In the 2 controlled trials in postherpetic neuralgia, 16% of the 336 patients who received gabapentin and 9% of the 227 patients who received placebo discontinued treatment because of an adverse reaction. The adverse reactions that most frequently led to withdrawal in RELGAABI-treated patients were dizziness, somnolence, and nausea.

Table 3 lists adverse reactions that occurred in at least 1% of gabapentin-treated patients with postherpetic neuralgia participating in placebo-controlled trials and that were numerically more frequent in the gabapentin group than in the placebo group.

TABLE 3. Adverse Reactions in Pooled Placebo-Controlled Trials in Postherpetic Neuralgia

	RELGAABI N=336 %	Placebo N=227 %
Body as a Whole		
Asthenia	6	5
Infection	5	4
Accidental injury	3	1
Digestive System		
Diarrhea	6	3
Dry mouth	5	1
Constipation	4	2
Nausea	4	3
Vomiting	3	2
Metabolic and Nutritional Disorders		
Peripheral edema	8	2
Weight gain	2	0
Hyperglycemia	1	0
Nervous System		
Dizziness	28	8
Somnolence	21	5
Ataxia	3	0
Abnormal thinking	3	0
Abnormal gait	2	0
Incoordination	2	0
Respiratory System		
Pharyngitis	1	0
Special Senses		
Amblyopiaa	3	1
Conjunctivitis	1	0
Diplopia	1	0
Otitis media	1	0

[a] Reported as blurred vision

Other reactions in more than 1% of patients but equally or more frequent in the placebo group included pain, tremor, neuralgia, back pain, dyspepsia, dyspnea, and flu syndrome.

There were no clinically important differences between men and women in the types and incidence of adverse reactions. Because there were few patients whose race was reported as other than white, there are insufficient data to support a statement regarding the distribution of adverse reactions by race.

Epilepsy with Partial Onset Seizures (Adjunctive Therapy)

The most common adverse reactions with gabapentin in combination with other antiepileptic drugs in patients > 12 years of age, not seen at an equivalent frequency among placebo-treated patients, were somnolence, dizziness, ataxia, fatigue, and nystagmus.

The most common adverse reactions with RELGAABI in combination with other antiepileptic drugs in pediatric patients 3 to 12 years of age, not seen at an equal frequency among placebo-treated patients, were viral infection, fever, nausea and/or vomiting, somnolence, and hostility [see Warnings and Precautions (5.9)].

Approximately 7% of the 2,074 patients > 12 years of age and approximately 7% of the 449 pediatric patients 3 to 12 years of age who received RELGAABI in premarketing clinical trials discontinued treatment because of an adverse reaction. The adverse reactions most commonly associated with withdrawal in patients > 12 years of age were somnolence (1.2%), ataxia

(0.8%), fatigue (0.6%), nausea and/or vomiting (0.6%), and dizziness (0.6%). The adverse reactions most commonly associated with withdrawal in pediatric patients were emotional lability (1.6%), hostility (1.3%), and hyperkinesia (1.1%).

Table 4 lists adverse reactions that occurred in at least 1% of RELGAABI-treated patients > 12 years of age with epilepsy participating in placebo-controlled trials and were numerically more common in the gabapentin group. In these studies, either RELGAABI or placebo was added to the patient's current antiepileptic drug therapy.

TABLE 4. Adverse Reactions in Pooled Placebo-Controlled Add-On Trials in Epilepsy Patients >12 Years of Age

	RELGAABI [a] N=543 %	Placebo [a] N=378 %
Body as a Whole		
Fatigue	11	5
Increased weight	3	2
Back pain	2	1
Peripheral edema	2	1
Cardiovascular		
Vasodilatation	1	0
Digestive System		
Dyspepsia	2	1
Dry mouth or throat	2	1
Constipation	2	1
Dental abnormalities	2	0
Nervous System		
Somnolence	19	9
Dizziness	17	7
Ataxia	13	6
Nystagmus	8	4
Tremor	7	3
Dysarthria	2	1
Amnesia	2	0
Depression	2	1
Abnormal thinking	2	1
Abnormal coordination	1	0
Respiratory System		
Pharyngitis	3	2
Coughing	2	1
Skin and Appendages		
Abrasion	1	0
Urogenital System		
Impotence	2	1
Special Senses		
Diplopia	6	2
Amblyopiab	4	1

[a] Plus background antiepileptic drug therapy.
[b] Amblyopia was often described as blurred vision.

Among the adverse reactions occurring at an incidence of at least 10% in gabapentintreated patients, somnolence and ataxia appeared to exhibit a positive dose-response relationship.

The overall incidence of adverse reactions and the types of adverse reactions seen were similar among men and women treated with RELGAABI. The incidence of adverse reactions increased slightly with increasing age in patients treated with either gabapentin or placebo. Because only 3% of patients (28/921) in placebo-controlled studies were identified as nonwhite (black or other), there are insufficient data to support a statement regarding the distribution of adverse reactions by race.

Table 5 lists adverse reactions that occurred in at least 2% of RELGAABI-treated patients, age 3 to 12 years of age with epilepsy participating in placebo-controlled trials, and which were numerically more common in the gabapentin group.

TABLE 5. Adverse Reactions in a Placebo-Controlled Add-On Trial in Pediatric Epilepsy Patients Age 3 to 12 Years

	RELGAABI [a] N=119 %	Placebo [a] N=128 %
Body as a Whole		
Viral infection	11	3
Fever	10	3
Increased weight	3	1
Fatigue	3	2
Digestive System		
Nausea and/or vomiting	8	7
Nervous System		
Somnolence	8	5
Hostility	8	2
Emotional lability	4	2
Dizziness	3	2
Hyperkinesia	3	1
Respiratory System		
Bronchitis	3	1
Respiratory infection	3	1

[a] Plus background antiepileptic drug therapy

Other reactions in more than 2% of pediatric patients 3 to 12 years of age but equally or more frequent in the placebo group included: pharyngitis, upper respiratory infection, headache, rhinitis, convulsions, diarrhea, anorexia, coughing, and otitis media.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postmarketing use of RELGAABI. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Hepatobiliary Disorders: jaundice

Investigations: elevated creatine kinase, elevated liver function tests

Metabolism and Nutrition Disorders: hyponatremia

Musculoskeletal and Connective Tissue Disorders: rhabdomyolysis

Nervous System Disorders: movement disorder

Psychiatric Disorders: agitation

Reproductive System and Breast Disorders: breast enlargement, changes in libido, ejaculation disorders and anorgasmia

Skin and Subcutaneous Tissue Disorders: angioedema [see Warnings and Precautions (5.2)], bullous pemphigoid, erythema multiforme, Stevens-Johnson syndrome.

There are postmarketing reports of life-threatening or fatal respiratory depression in patients taking RELGAABI with opioids or other CNS depressants, or in the setting of underlying respiratory impairment [see Warnings and Precautions (5.8)].

There are postmarketing reports of withdrawal symptoms after discontinuation of gabapentin. Reported adverse reactions include, but are not limited to, seizures, depression, suicidal ideation and behavior, agitation, confusion, disorientation, psychotic symptoms, anxiety, insomnia, nausea, pain, sweating, tremor, headache, dizziness, and malaise [see Warnings and Precautions (5.6)].

7 DRUG INTERACTIONS

7.1 Opioids

Respiratory depression and sedation, sometimes resulting in death, have been reported following coadministration of gabapentin with opioids (e.g., morphine, hydrocodone, oxycodone, buprenorphine) [see Warnings and Precautions (5.8)].

Hydrocodone

Coadministration of RELGAABI with hydrocodone decreases hydrocodone exposure [see Clinical Pharmacology (12.3)]. The potential for alteration in hydrocodone exposure and effect should be considered when RELGAABI is started or discontinued in a patient taking hydrocodone.

Morphine

When gabapentin is administered with morphine, patients should be observed for signs of CNS depression, such as somnolence, sedation and respiratory depression [see Clinical Pharmacology (12.3)].

7.2 Other Antiepileptic Drugs

Gabapentin is not appreciably metabolized nor does it interfere with the metabolism of commonly coadministered antiepileptic drugs [see Clinical Pharmacology (12.3)].

7.3 Maalox® (aluminum hydroxide, magnesium hydroxide)

The mean bioavailability of gabapentin was reduced by about 20% with concomitant use of an antacid (Maalox®) containing magnesium and aluminum hydroxides. It is recommended that gabapentin be taken at least 2 hours following Maalox® administration [see Clinical Pharmacology (12.3)].

7.4 Drug/Laboratory Test Interactions

Because false positive readings were reported with the Ames N-Multistix SG dipstick test for urinary protein when gabapentin was added to other antiepileptic drugs, the more specific sulfosalicylic acid precipitation procedure is recommended to determine the presence of urine protein.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

The totality of available data from published prospective and retrospective cohort studies pertaining to gabapentin use during pregnancy has not indicated an increased risk of major birth defects or miscarriage. There are important methodological limitations hindering interpretation of these studies [see Data]. In nonclinical studies in mice, rats, and rabbits, gabapentin was developmentally toxic (increased fetal skeletal and visceral abnormalities, and increased embryofetal mortality) when administered to pregnant animals at doses similar to or lower than those used clinically [see Data].

Postmarketing data suggest that extended gabapentin use with opioids close to delivery may increase the risk of neonatal withdrawal versus opioids alone [see Clinical Considerations]. Although there is at least one report of neonatal withdrawal syndrome in an infant exposed to gabapentin alone during pregnancy, there are no comparative epidemiologic studies evaluating this association. Therefore, whether exposure to gabapentin alone late in pregnancy may cause withdrawal signs and symptoms is not known.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Neonatal withdrawal syndrome has been reported in newborns exposed to gabapentin in utero for an extended period of time when also exposed to opioids close to delivery. Neonatal withdrawal signs and symptoms reported have included tachypnea, vomiting, diarrhea, hypertonia, irritability, sneezing, poor feeding, hyperactivity, abnormal sleep pattern, and tremor. Reported signs and symptoms that may also be related to withdrawal include tongue thrusting, wandering eye movements while awake, back arching, and continuous extremity movements. Observe neonates exposed to RELGAABI and opioids for signs and symptoms of neonatal withdrawal and manage accordingly.

Data

Human Data

An observational study based on routinely collected data from administrative and medical registers in Denmark, Finland, Norway, and Sweden, compared the prevalence of major congenital malformations in approximately 1,500 pregnancies exposed to gabapentin monotherapy in the first trimester to pregnancies unexposed to antiepileptics (n=2,995,816) and pregnancies exposed to lamotrigine monotherapy in the first trimester (n=7,582). The adjusted prevalence ratios in a pooled analysis were 1.00 (95% CI: 0.80-1.24) compared to pregnancies unexposed to antiepileptics and 1.29 (95% CI: 1.00-1.67) compared to pregnancies exposed to lamotrigine monotherapy in the first trimester.

Data from another observational study in the US based on Medicaid data, which compared the risk for major congenital malformations in more than 4,600 pregnancies exposed to gabapentin during the first trimester to unexposed pregnancies (n=1,753,865), estimated an adjusted relative risk of 1.07 (95% CI: 0.94-1.21).

Data from a cohort study of over 200,000 Medicaid-eligible pregnancies with prescription opioid exposure in the last 45 days of pregnancy found that the risk of neonatal drug withdrawal was greater in pregnancies with combined exposure to gabapentin and opioids compared to pregnancies with exposure to opioids alone.

The data from these observational studies should be interpreted with caution due to the potential for exposure misclassification, outcome misclassification, and residual confounding, including by underlying disease.

Animal Data

When pregnant mice received oral doses of gabapentin (500 mg/kg/day, 1,000 mg/kg/day, or 3,000 mg/kg/day) during the period of organogenesis, embryofetal toxicity (increased incidences of skeletal variations) was observed at the two highest doses. The no-effect dose for embryofetal developmental toxicity in mice (500 mg/kg/day) is less than

the maximum recommended human dose (MRHD) of 3,600 mg on a body surface area (mg/m) basis.

In studies in which rats received oral doses of gabapentin (500 mg/kg/day to 2,000 mg/kg/day) during pregnancy, adverse effect on offspring development (increased incidences of hydroureter and/or hydronephrosis) were observed at all doses. The lowest dose tested is similar to the MRHD on a mg/m basis.

When pregnant rabbits were treated with gabapentin during the period of organogenesis, an increase in embryofetal mortality was observed at all doses tested (60 mg/kg, 300 mg/kg, or 1,500 mg/kg). The lowest dose tested is less than the MRHD on a mg/m basis.

In a published study, gabapentin (400 mg/kg/day) was administered by intraperitoneal injection to neonatal mice during the first postnatal week, a period of synaptogenesis in rodents (corresponding to the last trimester of pregnancy in humans). Gabapentin caused a marked decrease in neuronal synapse formation in brains of intact mice and abnormal neuronal synapse formation in a mouse model of synaptic repair. Gabapentin has been shown in vitroto interfere with activity of the α2δ subunit of voltage-activated calcium channels, a receptor involved in neuronal synaptogenesis. The clinical significance of these findings is unknown.

8.2 Lactation

Risk Summary

RELGAABI in secreted in human milk following oral administration. The effects on the breastfed infant and on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RELGAABI and any potential adverse effects on the breastfed infant from gabapentin or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of RELGAABI in the management of postherpetic neuralgia in pediatric patients have not been established.

Safety and effectiveness as adjunctive therapy in the treatment of partial seizures in pediatric patients below the age of 3 years has not been established [see Clinical Studies (14.2)].

8.5 Geriatric Use

The total number of patients treated with RELGAABI in controlled clinical trials in patients with postherpetic neuralgia was 336, of which 102 (30%) were 65 to 74 years of age, and 168 (50%) were 75 years of age and older. There was a larger treatment effect in patients 75 years of age and older compared to younger patients who received the same dosage. Since gabapentin is almost exclusively eliminated by renal excretion, the larger treatment effect observed in patients ≥75 years may be a consequence of increased gabapentin exposure for a given dose that results from an age-related decrease in renal function. However, other factors cannot be excluded. The types and incidence of adverse reactions were similar across age groups except for peripheral edema and ataxia, which tended to increase in incidence with age.

Clinical studies of RELGAABI in epilepsy did not include sufficient numbers of subjects aged 65 and over to determine whether they responded differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and dose should be adjusted based on creatinine clearance values in these patients [see Dosage and Administration (2.4), Adverse Reactions (6), and Clinical Pharmacology (12.3)].

8.6 Renal Impairment

Dosage adjustment in adult patients with compromised renal function is necessary [see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)]. Pediatric patients with renal insufficiency have not been studied. Dosage adjustment in patients undergoing hemodialysis is necessary [see Dosage and Administration (2.3)and Clinical Pharmacology (12.3)].

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

RELGAABI contains gabapentin, which is not a controlled substance.

9.2 Abuse

Abuse is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed.

Gabapentin does not exhibit affinity for benzodiazepine, opioid (mu, delta or kappa), or cannabinoid 1 receptor sites. Gabapentin misuse and abuse have been reported in the postmarketing setting and published literature. Most of the individuals described in these reports had a history of polysubstance abuse. Some of these individuals were taking higher than recommended doses of gabapentin for unapproved uses. When prescribing RELGAABI carefully evaluate patients for a history of drug abuse and observe them for signs and symptoms of gabapentin misuse or abuse (e.g., self-dose escalation and drug-seeking behavior). The abuse potential of gabapentin has not been evaluated in human studies.

9.3 Dependence

Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

After discontinuation of short-term and long-term treatment with gabapentin, withdrawal symptoms have been observed in some patients. Withdrawal symptoms may occur shortly after discontinuation, usually within 48 hours. In the postmarketing setting, reported adverse reactions have included, but not been

limited to, seizures, depression, suicidal ideation and behavior, agitation, confusion, disorientation, psychotic symptoms, anxiety, insomnia, nausea, pain, sweating, tremor, headache, dizziness, and malaise. The dependence potential of gabapentin has not been evaluated in human studies.

10 OVERDOSAGE

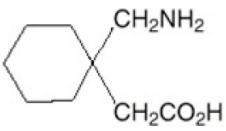
Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, or excitation. Acute oral overdoses of RELGAABI have been reported. Symptoms have included double vision, tremor, slurred speech, drowsiness, altered mental status, dizziness, lethargy, and diarrhea. Fatal respiratory depression has been reported with RELGAABI overdose, alone and in combination with other CNS depressants. Gabapentincan can be removed by hemodialysis. If overexposure occurs, call your poison control center at 1-800-222-1222.

11 DESCRIPTION

The active ingredient in RELGAABI capsules, USP is gabapentin, which has the chemical name 1-(aminomethyl) cyclohexaneacetic acid.

The molecular formula of gabapentin is $C_9H_{17}NO_2$ and the molecular weight is 171.24.

The structural formula of gabapentin is:



Gabapentin, USP is a white to off-white crystalline solid with a $pK_{a2}$of 4.72±0.10 and a $pK_{a1}$of 10.27±0.29. It is freely soluble in water and both basic and acidic aqueous solutions. The log of the partition coefficient is -1.083±0.235 at 25°C temperature.

Each RELGAABI capsule contains 100 mg, 200 mg, 300 mg or 400 mg of gabapentin, USP and the following inactive ingredients: pregelatinized starch (maize), and talc. The 100 mg capsule shell contains gelatin, sodium lauryl sulfate (SLS) and titanium dioxide. The 200 mg capsule shell contains gelatin, titanium dioxide, black and yellow iron oxide. The 300 mg capsule shell contains gelatin, titanium dioxide, FD&C Red 40, D&C Yellow 10, and sodium lauryl sulfate (SLS). The 400mg capsule shell contains gelatin, titanium dioxide, sodium lauryl sulfate (SLS), D&C Yellow 10, and FD&C Red 40. The imprinting ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, and potassium hydroxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The precise mechanism by which gabapentin produces its analgesic and antiepileptic actions are unknown. Gabapentin is structurally related to the neurotransmitter gammaaminobutyric acid (GABA) but has no effect on GABA binding, uptake, or degradation. In vitro studies have shown that gabapentin binds with high-affinity to the α2δ subunit of voltage-activated calcium channels; however, the relationship of this binding to the therapeutic effects of gabapentin is unknown.

12.3 Pharmacokinetics

All pharmacological actions following gabapentin administration are due to the activity of the parent compound; gabapentin is not appreciably metabolized in humans.

Oral Bioavailability

Gabapentin bioavailability is not dose proportional; i.e., as dose is increased, bioavailability decreases. Bioavailability of gabapentin is approximately 60%, 47%, 34%, 33%, and 27% following 900 mg/day, 1,200 mg/day, 2,400 mg/day, 3,600 mg/day, and 4,800 mg/day given in 3 divided doses, respectively. Food has only a slight effect on the rate and extent of absorption of gabapentin (14% increase in AUC and C_{max}).

Distribution

Less than 3% of gabapentin circulates bound to plasma protein. The apparent volume of distribution of gabapentin after 150 mg intravenous administration is 58±6 L (mean ±SD). In patients with epilepsy, steady-state predose (C_{min}) concentrations of gabapentin in cerebrospinal fluid were approximately 20% of the corresponding plasma concentrations.

Elimination

Gabapentin is eliminated from the systemic circulation by renal excretion as unchanged drug. Gabapentin is not appreciably metabolized in humans.

Gabapentin elimination half-life is 5 to 7 hours and is unaltered by dose or following multiple dosing. Gabapentin elimination rate constant, plasma clearance, and renal clearance are directly proportional to creatinine clearance. In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced.

Gabapentin can be removed from plasma by hemodialysis.

Specific Populations

Age

The effect of age was studied in subjects 20 to 80 years of age. Apparent oral clearance(CL/F) of gabapentin decreased as age increased, from about 225 mL/min in those under 30 years of age to about 125 mL/min in those over 70 years of age. Renal clearance (CLr) and CLr adjusted for body surface area also declined with age; however, the decline in the renal clearance of gabapentin with age can largely be explained by the decline in renal function. [see Dosage and Administration (2.4)and Use in Specific Populations (8.5)].

Gender

Although no formal study has been conducted to compare the pharmacokinetics of gabapentin in men and women, it appears that the pharmacokinetic parameters for males and females are similar and there are no significant gender differences.

Race

Pharmacokinetic differences due to race have not been studied. Because gabapentin is primarily renally excreted and there are no important racial differences in creatinine clearance, pharmacokinetic differences due to race are not expected.

Pediatric
Gabapentin pharmacokinetics were determined in 48 pediatric subjects between the ages of 1 month and 12 years following a dose of approximately 10 mg/kg. Peak plasma concentrations were similar across the entire age group and occurred 2 to 3 hours postdose. In general, pediatric subjects between 1 month and <5 years of age achieved approximately 30% lower exposure (AUC) than that observed in those 5 years of age and older. Accordingly, oral clearance normalized per body weight was higher in the younger children. Apparent oral clearance of gabapentin was directly proportional to creatinine clearance. Gabapentin elimination half-life averaged 4.7 hours and was similar across the age groups studied.

A population pharmacokinetic analysis was performed in 253 pediatric subjects between 1 month and 13 years of age. Patients received 10 mg/kg/day to 65 mg/kg/day given three times a day. Apparent oral clearance (CL/F) was directly proportional to creatinine clearance and this relationship was similar following a single dose and at steady-state. Higher oral clearance values were observed in children <5 years of age compared to those observed in children 5 years of age and older, when normalized per body weight. The clearance was highly variable in infants <1 year of age. The normalized CL/F values observed in pediatric patients 5 years of age and older were consistent with values observed in adults after a single dose. The oral volume of distribution normalized per body weight was constant across the age range.

These pharmacokinetic data indicate that the effective daily dose in pediatric patients with epilepsy ages 3 and 4 years should be 40 mg/kg/day to achieve average plasma concentrations similar to those achieved in patients 5 years of age and older receiving gabapentin at 30 mg/kg/day [see Dosage and Administration (2.2)].

Adult Patients with Renal Impairment
Subjects (N=60) with renal impairment (mean creatinine clearance ranging from 13 to 114 mL/min) were administered single 400 mg oral doses of gabapentin. The mean gabapentin half-life ranged from about 6.5 hours (patients with creatinine clearance >60 mL/min) to 52 hours (creatinine clearance < 30 mL/min) and gabapentin renal clearance from about 90 mL/min (>60 mL/min group) to about 10 mL/min (<30 mL/min). Mean plasma clearance (CL/F) decreased from approximately 190 mL/min to 20 mL/min [see Dosage and Administration (2.3)and Use in Specific Populations (8.6)]. Pediatric patients with renal insufficiency have not been studied.

Hemodialysis
In a study in anuric adult subjects (N=11), the apparent elimination half-life of gabapentin on nondialysis days was about 132 hours; during dialysis the apparent halflife of gabapentin was reduced to 3.8 hours. Hemodialysis thus has a significant effect on gabapentin elimination in anuric subjects. [see Dosage and Administration (2.3) and Use in Specific Populations (8.6)].

Hepatic Disease
Because gabapentin is not metabolized, no study was performed in patients with hepatic impairment.

Drug Interactions
- *In Vitro Studies*

In vitro studies were conducted to investigate the potential of gabapentin to inhibit the major cytochrome P450 enzymes (CYP1A2, CYP2A6, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4) that mediate drug and xenobiotic metabolism using isoform selective marker substrates and human liver microsomal preparations. Only at the highest concentration tested (171 mcg/mL; 1 mM) was a slight degree of inhibition (14% to 30%) of isoform CYP2A6 observed. No inhibition of any of the other isoforms tested was observed at gabapentin concentrations up to 171 mcg/mL (approximately 15 times the C_{max} at 3,600 mg/day).

- *In Vivo Studies*

The drug interaction data described in this section were obtained from studies involving healthy adults and adult patients with epilepsy.

Phenytoin
In a single (400 mg) and multiple dose (400 mg three times a day) study of gabapentin in epileptic patients (N=8) maintained on phenytoin monotherapy for at least 2 months, gabapentin had no effect on the steady-state trough plasma concentrations of phenytoin and phenytoin had no effect on gabapentin pharmacokinetics.

Carbamazepine
Steady-state trough plasma carbamazepine and carbamazepine 10, 11 epoxide concentrations were not affected by concomitant gabapentin (400 mg three times a day; N=12) administration. Likewise, gabapentin pharmacokinetics were unaltered by carbamazepine administration.

Valproic Acid
The mean steady-state trough serum valproic acid concentrations prior to and during concomitant gabapentin administration (400 mg three times a day; N=17) were not different and neither were gabapentin pharmacokinetic parameters affected by valproic acid.

Phenobarbital
Estimates of steady-state pharmacokinetic parameters for phenobarbital or gabapentin (300 mg three times a day; N=12) are identical whether the drugs are administered alone or together.

Naproxen
Coadministration (N=18) of naproxen sodium capsules (250 mg) with gabapentin (125 mg) appears to increase the amount of gabapentin absorbed by 12% to 15%. Gabapentin had no effect on naproxen pharmacokinetic parameters. These doses are lower than the therapeutic doses for both drugs. The magnitude of interaction within the recommended dose ranges of either drug is not known.

Hydrocodone
Coadministration of RELGAABI (125 mg to 500 mg; N=48) decreases hydrocodone (10 mg; N=50) C and AUC values in a dose-dependent manner relative to administration of hydrocodone alone; C and AUC values are 3% to 4% lower, respectively, after administration of 125 mg RELGAABI and 21% to 22% lower, respectively, after administration of

500 mg RELGAABI. The mechanism for this interaction is unknown. Hydrocodone increases gabapentin AUC values by 14%. The magnitude of interaction at other doses is not known.

Morphine

A literature article reported that when a 60 mg controlled-release morphine capsule was administered 2 hours prior to a 600 mg RELGAABI capsule (N=12), mean gabapentin AUC increased by 44% compared to RELGAABI administered without morphine. Morphine pharmacokinetic parameter values were not affected by administration of RELGAABI 2 hours after morphine. The magnitude of interaction at other doses is not known.

Cimetidine

In the presence of cimetidine at 300 mg four times a day (N=12), the mean apparent oral clearance of gabapentin fell by 14% and creatinine clearance fell by 10%. Thus, cimetidine appeared to alter the renal excretion of both gabapentin and creatinine, an endogenous marker of renal function. This decrease in excretion of gabapentin by cimetidine is not expected to be of clinical importance. The effect of gabapentin on cimetidine was not evaluated.

Oral Contraceptive

Based on AUC and half-life, multiple-dose pharmacokinetic profiles of norethindrone and ethinyl estradiol following administration of tablets containing 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol were similar with and without coadministration of gabapentin (400 mg three times a day; N=13). The C_{max} of norethindrone was 13% higher when it was coadministered with gabapentin; this interaction is not expected to be of clinical importance.

Antacid (Maalox®) (aluminum hydroxide, magnesium hydroxide)

Antacid (Maalox®) containing magnesium and aluminum hydroxides reduced the mean bioavailability of gabapentin (N=16) by about 20%. This decrease in bioavailability was about 10% when gabapentin was administered 2 hours after Maalox®.

Probenecid

Probenecid is a blocker of renal tubular secretion. Gabapentin pharmacokinetic parameters without and with probenecid were comparable. This indicates that gabapentin does not undergo renal tubular secretion by the pathway that is blocked by probenecid.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Gabapentin was administered orally to mice and rats in 2-year carcinogenicity studies. No evidence of drug-related carcinogenicity was observed in mice treated at doses up to 2,000 mg/kg/day. At 2,000 mg/kg, the plasma gabapentin exposure (AUC) in mice was approximately 2 times that in humans at the MRHD of 3,600 mg/day. In rats, increases in the incidence of pancreatic acinar cell adenoma and carcinoma were found in male rats receiving the highest dose (2,000 mg/kg), but not at doses of 250 or 1,000 mg/kg/day. At 1,000 mg/kg, the plasma gabapentin exposure (AUC) in rats was approximately 5 times that in humans at the MRHD.

Studies designed to investigate the mechanism of gabapentin-induced pancreatic carcinogenesis in rats indicate that gabapentin stimulates DNA synthesis in rat pancreatic acinar cells in vitroand, thus, may be acting as a tumor promoter by enhancing mitogenic activity. It is not known whether gabapentin has the ability to increase cell proliferation in other cell types or in other species, including humans.

Mutagenesis

Gabapentin did not demonstrate mutagenic or genotoxic potential in in vitro (Ames test, HGPRT forward mutation assay in Chinese hamster lung cells) and in vivo(chromosomal aberration and micronucleus test in Chinese hamster bone marrow, mouse micronucleus, unscheduled DNA synthesis in rat hepatocytes) assays.

Impairment of Fertility

No adverse effects on fertility or reproduction were observed in rats at doses up to 2,000 mg/kg. At 2,000 mg/kg, the plasma gabapentin exposure (AUC) in rats is approximately 8 times that in humans at the MRHD.

14 CLINICAL STUDIES

14.1 Postherpetic Neuralgia

RELGAABI was evaluated for the management of postherpetic neuralgia (PHN) in two randomized, double-blind, placebo-controlled, multicenter studies. The intent-to-treat (ITT) population consisted of a total of 563 patients with pain for more than 3 months after healing of the herpes zoster skin rash (Table 6).

TABLE 6. Controlled PHN Studies: Duration, Dosages, and Number of Patients

Study	Study Duration	Gabapentin (mg/day) [a] Target Dose	Patients Receiving Gabapentin	Patients Receiving Placebo
1	8 weeks	3600	113	116
2	7 weeks	1800, 2400	223	111
		Total	336	227

[a]Given in 3 divided doses (TID)

Each study included a 7- or 8-week double-blind phase (3 or 4 weeks of titration and 4 weeks of fixed dose). Patients initiated treatment with titration to a maximum of 900 mg/day gabapentin over 3 days. Dosages were then to be titrated in 600 to 1200 mg/day increments at 3- to 7-day intervals to the target dose over 3 to 4 weeks. Patients recorded their pain in a daily diary using an 11-point numeric pain rating scale ranging from 0 (no pain) to 10 (worst possible pain). A mean pain score during baseline of at least 4 was required for randomization. Analyses were conducted using the ITT population (all randomized patients who received at least one dose of study medication).

Both studies demonstrated efficacy compared to placebo at all doses tested.

The reduction in weekly mean pain scores was seen by Week 1 in both studies, and were maintained to the end of treatment. Comparable treatment effects were observed in all active treatment arms. Pharmacokinetic pharmacodynamic modeling provided confirmatory evidence of efficacy across

all doses. Figures 1 and 2 show pain intensity scores over time for Studies 1 and 2.

Figure 1. Weekly Mean Pain Scores (Observed Cases in ITT Population):

Study 1

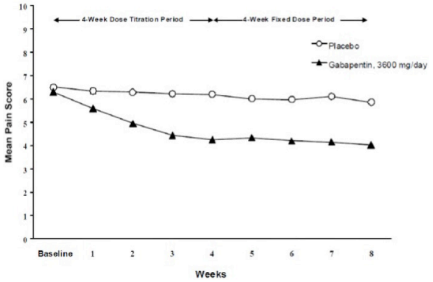
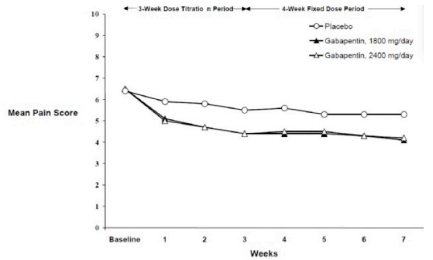


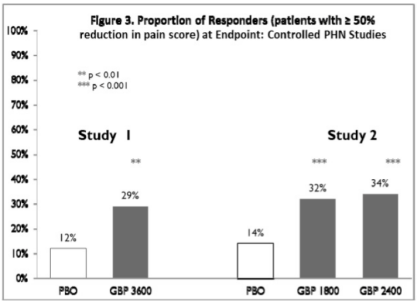
Figure 2. Weekly Mean Pain Scores (Observed Cases in ITT Population):

Study 2



The proportion of responders (those patients reporting at least 50% improvement in endpoint pain score compared to baseline) was calculated for each study (Figure 3).

Figure 3. Proportion of Responders (patients with ≥ 50% reduction in pain score) at Endpoint: Controlled PHN Studies



14.2 Epilepsy for Partial Onset Seizures (Adjunctive Therapy)

The effectiveness of RELGAABI as adjunctive therapy (added to other antiepileptic drugs) was established in multicenter placebo-controlled, double-blind, parallel-group clinical trials in adult and pediatric patients (3 years and older) with refractory partial seizures.

Evidence of effectiveness was obtained in three trials conducted in 705 patients (age 12 years and above) and one trial conducted in 247 pediatric patients (3 to 12 years of age). The patients enrolled had a history of at least 4 partial seizures per month in spite of receiving one or more antiepileptic drugs at therapeutic levels and were observed on their established antiepileptic drug regimen during a 12-week baseline period (6 weeks in the study of pediatric patients). In patients continuing to have at least 2 (or 4 in some studies) seizures per month, RELGAABI or placebo was then added on to the existing therapy during a 12-week treatment period. Effectiveness was assessed primarily on the basis of the percent of patients with a 50% or greater reduction in seizure frequency from baseline to treatment (the "responder rate") and a derived measure called response ratio, a measure of change defined as (T-B)/(T + B), in which B is the patient's baseline seizure frequency and T is the patient's seizure frequency during treatment. Response ratio is distributed within the range -1 to +1. A zero value indicates no change while complete elimination of seizures would give a value of -1; increased seizure rates would give positive values. A response ratio of -0.33 corresponds to a 50% reduction in seizure frequency. The results given below are for all partial seizures in the intent-totreat (all patients who received any doses of treatment) population in each study, unless otherwise indicated.

One study compared RELGAABI 1,200 mg/day, in three divided doses with placebo. Responder rate was 23% (14/61) in the RELGAABI group and 9% (6/66) in the placebo group; the difference between groups was statistically significant. Response ratio was also better in the RELGAABI group (-0.199) than in the placebo group (-0.044), a difference that also achieved statistical significance.

A second study compared primarily RELGAABI 1,200 mg/day, in three divided doses (N=101), with placebo (N=98). Additional smaller RELGAABI dosage groups (600 mg/day, N=53; 1,800 mg/day, N=54) were also studied for information regarding dose response. Responder rate was higher in the RELGAABI 1,200 mg/day group (16%) than in the placebo group (8%), but the difference was not statistically significant. The responder rate at 600 mg (17%) was also not significantly higher than in the placebo, but the responder rate in the 1,800 mg group (26%) was statistically significantly superior to the placebo rate. Response ratio was better in the RELGAABI 1,200 mg/day group (-0.103) than in the placebo group (-0.022); but this difference was also not statistically significant (p = 0.224). A better response was seen in the RELGAABI 600 mg/day group (-0.105) and 1,800 mg/day group (-0.222) than in the 1,200 mg/day group, with the 1,800 mg/day group achieving statistical significance compared to the placebo group.

A third study compared RELGAABI 900 mg/day, in three divided doses (N=111), and placebo (N=109). An additional RELGAABI 1,200 mg/day dosage group (N=52) provided dose-response data. A statistically significant difference in responder rate was seen in the RELGAABI 900 mg/day group (22%) compared to that in the placebo group (10%). Response ratio was also statistically significantly superior in the RELGAABI 900 mg/day group (-0.119) compared to that in the placebo group (-0.027), as was response ratio in 1,200 mg/day RELGAABI (-0.184) compared to placebo.

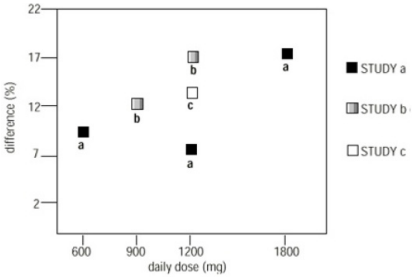
Analyses were also performed in each study to examine the effect of RELGAABI on preventing secondarily generalized tonic-clonic seizures. Patients who experienced a secondarily generalized tonic-clonic seizure in either the baseline or in the treatment period in all three placebo-controlled studies were included in these analyses. There were several response ratio

comparisons that showed a statistically significant advantage for RELGAABI compared to placebo and favorable trends for almost all comparisons.

Analysis of responder rate using combined data from all three studies and all doses (N=162, RELGAABI; N=89, placebo) also showed a significant advantage for RELGAABI over placebo in reducing the frequency of secondarily generalized tonic-clonic seizures.

In two of the three controlled studies, more than one dose of RELGAABI was used. Within each study, the results did not show a consistently increased response to dose. However, looking across studies, a trend toward increasing efficacy with increasing dose is evident (see Figure 4).

Figure 4. Responder Rate in Patients Receiving gabapentin Expressed as a Difference from Placebo by Dose and Study: Adjunctive Therapy Studies in Patients ≥12 Years of Age with Partial Seizures



In the figure, treatment effect magnitude, measured on the Y axis in terms of the difference in the proportion of gabapentin and placebo-assigned patients attaining a 50% or greater reduction in seizure frequency from baseline, is plotted against the daily dose of gabapentin administered (X axis).

Although no formal analysis by gender has been performed, estimates of response (Response Ratio) derived from clinical trials (398 men, 307 women) indicate no important gender differences exist. There was no consistent pattern indicating that age had any effect on the response to RELGAABI. There were insufficient numbers of patients of races other than Caucasian to permit a comparison of efficacy among racial groups.

A fourth study in pediatric patients age 3 to 12 years compared 25 to 35 mg/kg/day RELGAABI (N=118) with placebo (N=127). For all partial seizures in the intent-to-treat population, the response ratio was statistically significantly better for the RELGAABI group (-0.146) than for the placebo group (-0.079). For the same population, the responder rate for RELGAABI (21%) was not significantly different from placebo (18%). A study in pediatric patients age 1 month to 3 years compared 40 mg/kg/day RELGAABI (N=38) with placebo (N=38) in patients who were receiving at least one marketed antiepileptic drug and had at least one partial seizure during the screening period (within 2 weeks prior to baseline). Patients had up to 48 hours of baseline and up to 72 hours of double-blind video EEG monitoring to record and count the occurrence of seizures. There were no statistically significant differences between treatments in either the response ratio or responder rate.

16 HOW SUPPLIED/STORAGE AND HANDLING

RELGAABI (gabapentin) capsules, USP are supplied as follows:

100 mg capsules: White to off-white powder filled in size "3" hard gelatin capsules with opaque white colored cap and opaque white colored body imprinted SG on cap and 179 on body with black ink, available in: Bottles of 100: NDC 58657-232-01

200 mg capsules: White to off-white powder filled in size "2" hard gelatin capsules with opaque light yellow colored cap and opaque white colored body imprinted SG on cap and 607 on body withblack ink, available in: Bottles of 100: NDC 58657-231-01

300 mg capsules: White to off-white powder filled in size "1" hard gelatin capsules with opaque yellow colored cap and opaque yellow colored body imprinted SG on cap and 180 on body with black ink, available in: Bottles of 100: NDC 58657-233-01

400 mg capsules: White to off-white powder filled in size "0" hard gelatin capsules with opaque orange colored cap and opaque orange colored body imprinted SG on cap and 181 on body with black ink, available in: Bottles of 100: NDC 58657-234-01

Store RELGAABI capsules at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Administration Information

Inform patients that RELGAABI is taken orally with or without food.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Prior to initiation of treatment with RELGAABI, instruct patients that a rash or other signs or symptoms of hypersensitivity (such as fever or lymphadenopathy) may herald a serious medical event and that the patient should report any such occurrence to a healthcare provider immediately [see Warnings and Precautions (5.1)].

Anaphylaxis and Angioedema

Advise patients to discontinue RELGAABI and seek medical care if they develop signs or symptoms of anaphylaxis or angioedema [see Warnings and Precautions (5.2)].

Dizziness and Somnolence and Effects on Driving and Operating Heavy Machinery

Advise patients that RELGAABI may cause dizziness, somnolence, and other symptoms and signs of CNS depression. Other drugs with sedative properties may increase these symptoms. Accordingly, although patients' ability to determine their level of impairment can be unreliable, advise them neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on RELGAABI to gauge whether or not it affects their mental and/or motor performance adversely. Inform patients that it is not known how long this effect lasts [see Warnings and Precautions (5.3)and Warnings and Precautions (5.4)].

Suicidal Thinking and Behavior
Counsel the patient, their caregivers, and families that AEDs, including RELGAABI, may increase the risk of suicidal thoughts and behavior. Advise patients of the need to be alert for the emergence or worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Instruct patients to report behaviors of concern immediately to healthcare providers [see Warnings and Precautions (5.5)]. Also, inform patients who plan to or have discontinued RELGAABI that suicidal thoughts and behavior can appear even after the drug is stopped.

Respiratory Depression
Inform patients about the risk of respiratory depression. Include information that the risk is greatest for those using concomitant CNS depressants (such as opioid analgesics) or those with underlying respiratory impairment. Teach patients how to recognize respiratory depression and advise them to seek medical attention immediately if it occurs [see Warnings and Precautions (5.8)].

Use in Pregnancy
Instruct patients to notify their healthcare provider if they become pregnant or intend to become pregnant during therapy, and to notify their healthcare provider if they are breast feeding or intend to breast feed during therapy [see Use in Specific Populations (8.1) and (8.2)].

Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788

Manufactured for:
Method Pharmaceuticals
Southlake, TX 76092

Rev: 2/2026

MEDICATION GUIDE
RELGAABI (rel gah' bee)
(gabapentin)
Capsules, for oral use

What is the most important information I should know about RELGAABI?

Do not stop taking RELGAABI without first talking to your healthcare provider. Stopping RELGAABI suddenly can cause serious problems.

RELGAABI can cause serious side effects including:
1) Suicidal Thoughts. Like other antiepileptic drugs, RELGAABI may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. This can happen while you take RELGAABI as well as after stopping RELGAABI.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:
- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?
- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Do not stop taking RELGAABI without first talking to a healthcare provider.
- Stopping RELGAABI suddenly can cause serious problems. Stopping a seizure medicine suddenly in a person who has epilepsy can cause seizures that will not stop (status epilepticus).
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

2) Changes in behavior and thinking. Using RELGAABI in children 3 to 12 years of age can cause emotional changes, aggressive behavior, problems with concentration, changes in school performance, restlessness, and hyperactivity.

3) RELGAABI may cause serious or life-threatening allergic reactions that may affect your skin or other parts of your body such as your liver or blood cells. This may cause you to be hospitalized or to stop RELGAABI. You may or may not have a rash with an allergic reaction caused by RELGAABI. Call a healthcare provider right away if you have any of the following symptoms:
- skin rash
- hives
- difficulty breathing
- fever
- swollen glands that do not go away
- swelling of your face, lips, throat, or tongue
- yellowing of your skin or of the whites of the eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- unexpected muscle pain
- frequent infections

These symptoms may be the first signs of a serious reaction. A healthcare provider
should examine you to decide if you should continue taking RELGAABI.

4) Serious breathing problems. Serious breathing problems can happen when RELGAABI is taken with other medicines (such as opioid pain medicines) that can cause severe sleepiness or decreased awareness, or when it is taken by someone who already has breathing problems. Call your healthcare provider or get medical help right away if you have any of the following symptoms:

- feel short of breath
- feel very tired
- dizziness
- breathing slower than normal
- confusion
- headache

Be sure that your caregiver or family members know which symptoms may be serious so they can call your healthcare provider or get medical help if you are unable to seek treatment on your own.

Your healthcare provider may lower your dose or stop your treatment with RELGAABI if you have serious breathing problems.

What is RELGAABI?
RELGAABI is a prescription medicine used to treat:
- pain from damaged nerves (postherpetic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection) in adults.
- artial seizures when taken together with other medicines in adults and children 3 years of age and older with seizures.

It is not known if RELGAABI is safe and effective to treat:
- children with pain from damaged nerves from a painful rash caused by the chicken pox virus.
- partial seizures in children under 3 years of age.

Do not take RELGAABI if you:
- are allergic to gabapentin or any of the other ingredients in RELGAABI.

See the end of this Medication Guide for a complete list of ingredients in RELGAABI.

Before taking RELGAABI, tell your healthcare provider about all of your medical conditions including if you:
- have or have had kidney problems or are on hemodialysis.
- have or have had depression, mood problems, or suicidal thoughts or behavior.
- have a history of drug abuse.
- have diabetes.
- have breathing problems.
- are pregnant or plan to become pregnant. It is not known if RELGAABI can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking RELGAABI. You and your healthcare provider will decide if you should take RELGAABI while you are pregnant.
- are breastfeeding or plan to breastfeed. RELGAABI can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you take RELGAABI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Especially tell your healthcare provider if you take:
- any opioid pain medicine such as morphine, hydrocodone, oxycodone, or buprenorphine.
- any medicines for anxiety (such as lorazepam) or insomnia (such as zolpidem), or any medicines that make you sleepy. You may have a higher chance for dizziness, sleepiness, or breathing problems if these medicines are taken with RELGAABI.

Taking RELGAABI with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take RELGAABI?
- Take RELGAABI exactly as prescribed. Your healthcare provider will tell you how much RELGAABI to take.
- Do not change your dose of RELGAABI without talking to your healthcare provider.
- Do not stop taking RELGAABI without talking to your healthcare provider first. If you stop taking RELGAABI suddenly, you may develop side effects.
- RELGAABI can be taken with or without food.
- Swallow RELGAABI capsules whole with water.
- If you take an antacid containing aluminum and magnesium, such as Maalox, Mylanta, Gelusil, Gaviscon, or Di-Gel, you should wait at least 2 hours before taking your next dose of RELGAABI.
- In case of overdose, get medical help or contact a live Poison Center expert right away at 1-800-222-1222. Advice is also available online at poisonhelp.org.

What should I avoid while taking RELGAABI?
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking RELGAABI without first talking with your healthcare provider. Taking RELGAABI with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how RELGAABI affects you. RELGAABI can slow your thinking and motor skills.

What are the possible side effects of RELGAABI?
RELGAABI may cause serious side effects, including:
- See "What is the most important information I should know about RELGAABI?"
- problems driving while using RELGAABI. See "What should I avoid while taking RELGAABI?"
- sleepiness and dizziness, which could increase yourchance of having an accidental injury, including falls.

The most common side effects of RELGAABI include:
- lack of coordination
- feeling drowsy
- viral infection
- nausea and vomiting
- difficulty with speaking
- jerky movements
- tremor
- difficulty with coordination
- swelling, usually of legs and feet
- double vision
- feeling tired
- unusual eye movement
- fever

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of RELGAABI. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RELGAABI?
Store RELGAABI capsules at room temperature between 68°F to 77°F (20°C to 25°C). Keep RELGAABI and all medicines out of the reach of children.

General information about the safe and effective use of RELGAABI.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RELGAABI for a condition for which it was not prescribed.

Do not give RELGAABI to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about RELGAABI that is written for health professionals.

What are the ingredients in RELGAABI?
Active ingredient: gabapentin USP
Inactive ingredients in the capsules: Pregelatinized starch (maize) and talc.
- The 100-mg capsule shell also contains: gelatin, sodium lauryl sulfate (SLS), titanium dioxide.
- The 200-mg capsule shell also contains gelatin, titanium dioxide, black and yellow iron oxide.
- The 300-mg capsule shell also contains: gelatin, titanium dioxide, FD&C Red 40, D&C Yellow 10, and sodium lauryl sulfate (SLS).
- The 400-mg capsule shell also contains: gelatin, titanium dioxide, sodium lauryl sulfate (SLS), D&C Yellow 10, and FD&C Red 40. The imprinting ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, and potassium hydroxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788

Manufactured for:
Method Pharmaceuticals
Southlake, TX 76092

Revised: 3/2026

Package/Label Display Panel

NDC 58657-231-01
RELGAABI
(gabapentin) Capsules, USP
200 mg
100 ct

NDC 58657-233-01
RELGAABI
(gabapentin) Capsules, USP
300 mg
100 ct

NDC 58657-234-01
RELGAABI
(gabapentin) Capsules, USP
400 mg
100 ct