TRIFLUENT PHARMA®



Non-Steroidal Alternative for Treating Pruritus

Help patients find relief from:

Pruritus — **Scabies**

COPAY INFORMATION

PATIENTS May Pay As Little As $0*

*Full terms and conditions at trifluentpharma.com/copay

Pruradik™

(Crotamiton 10%) Lotion 237 gm

NDC: 73352-051-10

INDICATIONS:

For eradication of scabies (*Sarcoptes scabiei*) and for symptomatic treatment of pruritic skin.

CONTRAINDICATIONS:

Pruradik lotion should not be applied topically to patients who develop a sensitivity or are allergic to it or who manifest a primary irritation response to topical medications.

WARNINGS:

If severe irritation or sensitization develops, treatment with this product should be discontinued and appropriate therapy instituted.

See full Prescribing Information on back.

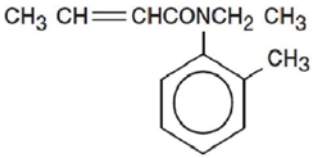
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088.

Pruradik™- crotamiton lotion
Trifluent Pharma, LLC

PRURADIK™ LOTION FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.
Rx ONLY

Pruradik™ (crotamiton USP 10%) is a scabicidal and antipruritic agent as a lotion for topical use only. Crotamiton is a colorless to slightly yellowish oil, having a faint amine-like odor. It is miscible with alcohol and with methanol. Crotamiton is a mixture of the *cis* and *trans* isomers. Its molecular weight is 203.28. Crotamiton is N-ethyl-N(o-methyl-phenyl) 2-butenamide and its structural formula is:

Pruradik™ lotion contains crotamiton USP 10% (100 mg/ml) in a creamy lotion base containing purified water, light mineral oil, propylene glycol, cetearyl alcohol (and) ceteareth-20, cetyl alcohol, lanolin, benzyl alcohol, carbomer 971P, sodium hydroxide with citric acid (for pH adjustment).



CLINICAL PHARMACOLOGY: Pruradik™ lotion has scabicidal and antipruritic actions. The mechanisms of these actions are not known. The pharmacokinetics of crotamiton and its degree of systemic absorption following topical application have not been determined.

Geriatric Use: Clinical studies with Pruradik™ (crotamiton USP) lotion did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS: Primary irritation reactions such as dermatitis, pruritus and rash, and allergic sensitivity reactions have been reported in a few patients. To report SUSPECTED ADVERSE REACTIONS, contact Trifluent Pharma, LLC at 1-888-927-5191 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE: There is no specific information on the effect of overtreatment with repeated topical applications in humans. A death was reported but cause was not confirmed. Accidental oral ingestion may be accompanied by burning sensation in the mouth, irritation of the buccal, esophageal and gastric mucosa, nausea, vomiting, abdominal pain. If accidental ingestion occurs, call your Poison Control Center.

DOSAGE AND ADMINISTRATION:
SHAKE WELL BEFORE USE.

In Scabies: Thoroughly massage into the skin of the whole body, from the chin down, paying particular attention to all folds and creases. A second application is advisable 24 hours later. Clothing and bed linen should be changed the next morning. A cleansing bath should be taken 48 hours after the last application.

In Pruritus: Massage gently into affected areas until medication is completely absorbed. Repeat as needed.

DIRECTIONS FOR PATIENTS WITH SCABIES:

1. Take a routine bath or shower. Thoroughly massage Pruradik™ lotion into the skin from the chin to the toes including folds and creases.
2. Put Pruradik™ lotion under fingernails after trimming the fingernails short, because scabies are likely to remain there. A toothbrush can be used to apply the Pruradik™ lotion under the fingernails. Immediately after use, the toothbrush should be wrapped in paper and thrown away. Use of the brush in the mouth could lead to poisoning.
3. A second application is advisable 24 hours later.
4. Clothing and bed linen should be changed the next day. Contaminated clothing and bed linen may be dry-cleaned or washed in the hot cycle of the washing machine.
5. A cleansing bath should be taken 48 hours after the last application.

INDICATIONS AND USAGE: For eradication of scabies *(Sarcoptes scabiei)* and for symptomatic treatment of pruritic skin.

CONTRAINDICATIONS: Pruradik™ lotion should not be applied topically to patients who develop a sensitivity or are allergic to it or who manifest a primary irritation response to topical medications.

WARNINGS: If severe irritation or sensitization develops, treatment with this product should be discontinued and appropriate therapy instituted.

PRECAUTIONS:

GENERAL: Pruradik™ lotion should not be applied in the eyes or mouth because it may cause irritation. It should not be applied to acutely inflamed skin or raw or weeping surfaces until acute inflammation has subsided.

Information for Patients: See **"DIRECTIONS FOR PATIENTS WITH SCABIES."**

DRUG INTERACTIONS: None known.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long-term carcinogenicity studies in animals have not been conducted.

PREGNANCY (CATEGORY C): Animal reproduction studies have not been conducted with Pruradik™ (crotamiton USP) lotion. It is also not known whether Pruradik™ can cause fetal harm when applied to a pregnant woman or can affect reproduction capacity. Pruradik™ should be given to a pregnant woman only if clearly needed.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

HOW SUPPLIED: Pruradik™ (crotamiton USP) lotion, 10% is available in: 237 gm (**NDC:** 73352-051-10)

Rx ONLY

Distributed By:

Trifluent Pharma, LLC
San Antonio, TX 78213

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KEEP OUT OF REACH OF CHILDREN.

STORAGE: Store 20°C to 25°C (68°F - 77°F). Excursions allowed between 15°C and 30°C (59°F and 86°F) [See USP Controlled Room Temperature].

HOW TO WRITE
FOR PRURITUS:

Pruradik

Apply a thin layer to the affected area 2 to 3 times daily.

☐ 10%

Dispense as written

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TRIFLUENTPHARMA.COM

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