MEZTAS 1.2 g

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MEZTAS 1.2 g?

MEZTAS 1.2 g contains the active ingredient mesalazine. MEZTAS 1.2 g is used for the treatment of ulcerative colitis. For more information, see Section 1. Why am I using MEZTAS 1.2 g? in the full CMI.

2. What should I know before I use MEZTAS 1.2 g?

Do not use if you have ever had an allergic reaction to MEZTAS 1.2 g or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MEZTAS 1.2 g? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MEZTAS 1.2 g and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use MEZTAS 1.2 g?

- Your doctor will tell you what dose to take each day.
- Take your tablets with or without food at the same time each day. The tablets must be swallowed whole and must not be crushed or chewed. Follow all directions given to you by your pharmacist or doctor carefully.

More instructions can be found in Section 4. How do I use MEZTAS 1.2 g? in the full CMI.

5. What should I know while using MEZTAS 1.2 g?

Things you should do	• Remind any doctor or dentist you visit that you are using MEZTAS 1.2 g. If you are pregnant or intend to become pregnant while using this medicine, tell the doctor immediately.
Things you should not do	• Do not stop using this medicine suddenly or change the dosage without checking with your doctor.
Driving or using machines	• MEZTAS 1.2 g is unlikely to have any effect on your ability to drive or use machines.
Looking after your medicine	• Store MEZTAS 1.2 g in a cool dry place where the temperature is below 25°C.

For more information, see Section 5. What should I know while using MEZTAS 1.2 g? in the full CMI.

6. Are there any side effects?

Common side effects include headache, tiredness, indigestion, mild stomach pains, excessive gas in the stomach or bowel, increased number of bowel motions, nausea, vomiting, rash or itchy skin, fever, loss of strength, muscle or joint or back pain.

Serious side effects include acute intolerance syndrome symptoms such as cramping, severe stomach pain, bloody and excessive stools (diarrhoea), fever, headache or rash, unexplained bruising, rash, anaemia, sore throat, unusual bleeding, allergic reaction, severe pain in the back side or stomach, trouble urinating, pain or burning during urination, increased blood pressure.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

MEZTAS 1.2 g

Active ingredient(s): mesalazine

Consumer Medicine Information (CMI)

This leaflet provides important information about using MEZTAS 1.2 g. It does not take the place of talking to your doctor or pharmacist. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MEZTAS 1.2 g.** The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

1. Why am I using MEZTAS 1.2 g?
2. What should I know before I use MEZTAS 1.2 g?
3. What if I am taking other medicines?
4. How do I use MEZTAS 1.2 g?
5. What should I know while using MEZTAS 1.2 g?
6. Are there any side effects?
7. Product details

1. Why am I using MEZTAS 1.2 g?

MEZTAS 1.2 g contains the active ingredient mesalazine (also called 5-aminosalicylic acid or 5-ASA).

MEZTAS 1.2 g is an anti-inflammatory drug used for the treatment of ulcerative colitis. When MEZTAS 1.2 g is taken for a flare up of ulcerative colitis, it acts through the entire colon and rectum to treat the inflammation and reduce symptoms. MEZTAS 1.2 g can also be taken to help prevent re-occurrence of ulcerative colitis.

2. What should I know before I use MEZTAS 1.2 g?

Warnings

Do not use MEZTAS 1.2 g if:

1. you are allergic to mesalazine, or any of the ingredients listed at the end of this leaflet.
2. you are allergic to a family of drugs known as salicylates (which include aspirin).
3. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any kidney problems
- have previously had inflammation of the heart (which may be the result of an infection in the heart)
- have had a previous allergic reaction to MEZTAS 1.2 g or other medicines containing mesalazine or sulphasalazine (other medicines taken for treatment of ulcerative colitis)
- have narrowing or blockage of the stomach or the gut
- have skin conditions such as atopic dermatitis or atopic eczema
- have ever developed severe skin rash or skin peeling, blistering and/or mouth sores
- have any other medical conditions or take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with MEZTAS 1.2 g and affect how it works.

These include:

- mesalazine or sulphasalazine (taken for treatment of ulcerative colitis)
- non-steroidal anti-inflammatory drugs (for example medicines containing aspirin, ibuprofen or diclofenac)
- azathioprine or 6-mercaptopurine (known as 'immunosuppressant' medicines).
- warfarin (taken to prevent blood clots) or other coumarin-type anticoagulants

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MEZTAS 1.2 g.

4. How do I use MEZTAS 1.2 g?

How much to take

- Adults and the elderly:
  The usual daily dose for adults and the elderly is 2.4g to 4.8g (two to four tablets) taken once a day for an acute episode of ulcerative colitis. If you are taking the highest daily dose of 4.8g/day, you should be evaluated after 8 weeks of treatment. Once your symptoms have cleared and to help prevent re-occurrence of another episode, your doctor may direct you to take 2.4g (two tablets) once a day.

Children and Adolescents:
MEZTAS 1.2 g is not recommended to be given to children under 18 years of age due to lack of data on safety and efficacy.

- Follow the instructions provided and use MEZTAS 1.2 g until your doctor tells you to stop.

When to take MEZTAS 1.2 g

- Take MEZTAS 1.2 g at the same time each day. It is important to take MEZTAS 1.2 g every day for as long as your doctor tells you to, even when you don't have any symptoms of ulcerative colitis.

How to take MEZTAS 1.2 g

- MEZTAS 1.2 g can be taken with or without food. The tablets must be swallowed whole and must not be crushed or chewed.

If you forget to use MEZTAS 1.2 g

MEZTAS 1.2 g should be used regularly at the same time each day. If you miss your dose at the usual time, then take them as usual the next day.

Do not take a double dose to make up for the dose you missed.

If you use too much MEZTAS 1.2 g

If you think that you have used too much MEZTAS 1.2 g, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MEZTAS 1.2 g?

Things you should do

- make sure that all of your doctors, dentists, and pharmacists know you are taking MEZTAS 1.2 g. Remind them if any new medicines are about to be started.
- ensure adequate fluid intake during treatment.

Things you should not do

- do not stop using this medicine suddenly or change the dosage without checking with your doctor.
- do not give to children under 18 years of age. MEZTAS 1.2 g is not suitable for children under 18 years of age as there is not enough information on its effects in children.
- do not give MEZTAS 1.2 g to anyone else, even if they have the same condition as you. It may not be safe for another person to take MEZTAS 1.2 g.
- do not take MEZTAS 1.2 g to treat any other complaints unless your doctor tells you to. It may not be safe to use MEZTAS 1.2 g for another complaint.

Driving or using machines

MEZTAS 1.2 g is unlikely to have any effect on your ability to drive or use machines.

Looking after your medicine

Keep MEZTAS 1.2 g tablets in the pack until it is time to take them. Store MEZTAS 1.2 g in a cool dry place where the temperature stays below 25°C.

Do not store it in the bathroom or near a sink, or in the car or on windowsill.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• headache • tiredness • indigestion • mild stomach pains • bloating or passing wind • excessive gas in the stomach or bowel • increased number of bowel motions • nausea • vomiting • rash or itchy skin • fever • loss of strength • muscle, joint or back pain • Trouble urinating, • Pain or burning during urination.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• severe stomach pain • cramping, bloody stools and diarrhoea • Unexplained bruising without injury • feeling tired, weak and pale (especially on lips nails and insides of eyelids) • unusual bleeding • Signs of hypersensitivity including: swelling of eyes, face, lips, mouth, tongue or throat difficulty in swallowing or breathing • widespread rash with blistering of the skin, particularly around the mouth, eyes and genitals • allergic skin rash with fever • severe pain in the back, side or stomach. • increased blood pressure • circular, reddish no-elevated patches on trunk which may have a central blister with or without flu-like symptoms	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• skin peeling with or without flu-like symptoms • ulcers of mouth, nose, genitals and eyes with or without flu-like symptoms.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What MEZTAS 1.2 g contains

Active ingredient (main ingredient)	Mesalazine
Other ingredients (inactive ingredients)	magnesium stearate, sodium starch glycolate, hypromellose, microcrystalline cellulose, colloidal anhydrous silica, methacrylic acid copolymer, triethyl citrate, purified talc, carmellose sodium, and OPADRY Complete film coating system 03F565028

Do not take this medicine if you are allergic to any of these ingredients.

What **MEZTAS 1.2 g** looks like

MEZTAS 1.2 g tablet (AUST R 442794 and AUST R 442795): Pale red-brown, oval shaped, biconvex, bevel film coated tablets debossed with the '711' on one side and plain on other side.

MEZTAS 1.2 g is supplied as 60 or 120 tablets pack size.

Who distributes MEZTAS 1.2 g

MedTas Pty Ltd
5B, 91-3 Redmyre Road
Strathfield NSW 2135

This leaflet was prepared in March 2025.