

# MESALAZINE 1.2 TAKEDA

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## **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.

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### **1. Why am I using MESALAZINE 1.2 TAKEDA?**

MESALAZINE 1.2 TAKEDA contains the active ingredient mesalazine. MESALAZINE 1.2 TAKEDA is used for the treatment of ulcerative colitis.

For more information, see Section [1. Why am I using MESALAZINE 1.2 TAKEDA?](#) in the full CMI.

### **2. What should I know before I use MESALAZINE 1.2 TAKEDA?**

Do not use if you have ever had an allergic reaction to MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA?

- 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 MESALAZINE 1.2 TAKEDA?](#) in the full CMI.

### 5. What should I know while using MESALAZINE 1.2 TAKEDA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or dentist you visit that you are using MESALAZINE 1.2 TAKEDA. If you are pregnant or intend to</li></ul>
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	become pregnant while using this medicine, tell the doctor immediately.
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly or change the dosage without checking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• MESALAZINE 1.2 TAKEDA is unlikely to have any effect on your ability to drive or use machines.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store MESALAZINE 1.2 TAKEDA in a cool dry place where the temperature is below 25°C.</li> </ul>

For more information, see Section [5. What should I know while using MESALAZINE 1.2 TAKEDA?](#) 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.

# MESALAZINE 1.2 TAKEDA

**Active ingredient(s):** mesalazine

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using MESALAZINE 1.2 TAKEDA. 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 MESALAZINE 1.2 TAKEDA.**

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. You can also download the most up to date leaflet from [www.takeda.com/en-au](http://www.takeda.com/en-au). 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 MESALAZINE 1.2 TAKEDA?](#)
- [2. What should I know before I use MESALAZINE 1.2 TAKEDA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MESALAZINE 1.2 TAKEDA?](#)
- [5. What should I know while using MESALAZINE 1.2 TAKEDA?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

## **1. Why am I using MESALAZINE 1.2 TAKEDA?**

**MESALAZINE 1.2 TAKEDA contains the active ingredient mesalazine (also called 5-aminosalicylic acid or 5-ASA).**

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

## **2. What should I know before I use MESALAZINE 1.2 TAKEDA?**

### **Warnings**

**Do not use MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA.**

### **4. How do I use MESALAZINE 1.2 TAKEDA?**

#### **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:

MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA until your doctor tells you to stop.

## **When to take MESALAZINE 1.2 TAKEDA**

- Take MESALAZINE 1.2 TAKEDA at the same time each day. It is important to take MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA**

- MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA**

MESALAZINE 1.2 TAKEDA 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 MESALAZINE 1.2 TAKEDA**

If you think that you have used too much MESALAZINE 1.2 TAKEDA, 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 MESALAZINE 1.2 TAKEDA?**

### **Things you should do**

- make sure that all of your doctors, dentists, and pharmacists know you are taking MESALAZINE 1.2

TAKEDA. 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. MESALAZINE 1.2 TAKEDA is not suitable for children under 18 years of age as there is not enough information on its effects in children.
- do not give MESALAZINE 1.2 TAKEDA to anyone else, even if they have the same condition as you. It may not be safe for another person to take MESALAZINE 1.2 TAKEDA.
- do not take MESALAZINE 1.2 TAKEDA to treat any other complaints unless your doctor tells you to. It may not be safe to use MESALAZINE 1.2 TAKEDA for another complaint.

## **Driving or using machines**

MESALAZINE 1.2 TAKEDA is unlikely to have any effect on your ability to drive or use machines.

## **Looking after your medicine**

Keep MESALAZINE 1.2 TAKEDA tablets in the pack until it is time to take them. Store MESALAZINE 1.2 TAKEDA 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**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• headache</li><li>• tiredness</li><li>• indigestion</li><li>• mild stomach pains</li><li>• bloating or passing wind</li><li>• excessive gas in the stomach or bowel</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• increased number of bowel motions</li> <li>• nausea</li> <li>• vomiting</li> <li>• rash or itchy skin</li> <li>• fever</li> <li>• loss of strength</li> <li>• muscle, joint or back pain</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• if you experience symptoms such as cramping, severe stomach pain, bloody and excessive stools (diarrhoea), fever, headache or rash. These symptoms could be a sign of Acute Intolerance Syndrome which can happen during an acute episode of ulcerative colitis. This is a serious condition which occurs rarely, but</li> </ul>	<p><b>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.</b></p>

Serious side effects	What to do
<p>means your treatment would have to be stopped immediately</p> <ul style="list-style-type: none"> <li>• if you develop unexplained bruising (without injury), rash, anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids), fever (high temperature), sore throat or unusual bleeding (e.g. nose bleeds)</li> <li>• if you develop allergic swelling of face, eyes, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.</li> <li>• widespread rash with blistering of the skin, particularly around the mouth, eyes and genitals</li> <li>• allergic skin rash with fever</li> <li>• severe pain in the back, side or stomach. Trouble urinating,</li> </ul>	

Serious side effects	What to do
<p>pain or burning during urination. These could be symptoms of kidney stones</p> <ul style="list-style-type: none"> <li>● increased blood pressure</li> <li>● If you notice reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms. Your treatment will need to be stopped immediately if you experience these serious conditions.</li> <li>● If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
(idiopathic intracranial hypertension).	

**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](http://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 MESALAZINE 1.2 TAKEDA contains**

<b>Active ingredient</b>	Mesalazine
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	Carmellose sodium, carnauba wax, stearic acid, silicon dioxide, sodium starch glycollate, talc-purified, magnesium stearate, methacrylic acid copolymer, triethyl citrate, titanium dioxide (E171), iron oxide red (CI77491), Macrogol 6000

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

## **What MESALAZINE 1.2 TAKEDA looks like**

MESALAZINE 1.2 TAKEDA 1.2 g tablet (AUST R 316122): Oval shaped red-brown tablets which are stamped with S476.

MESALAZINE 1.2 TAKEDA is supplied as a 60 tablets pack size.

## **Who distributes MESALAZINE 1.2 TAKEDA**

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Australia

Phone: 1800 012 612

[www.takeda.com/en-au](http://www.takeda.com/en-au)

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