

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 taking MESASAL?

MESASAL contains the active ingredient mesalazine. MESASAL is used to treat acute inflammatory bowel disease and for regular treatment of Crohn's disease and ulcerative colitis.

For more information, see Section [1. Why am I taking MESASAL?](#) in the full CMI.

2. What should I know before I take MESASAL?

Do not take if you have ever had an allergic reaction to mesalazine, or any other aspirin-line medicines, 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 take MESASAL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MESASAL 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 take MESASAL?

- For acute ulcerative colitis and Crohn's disease: Take two tablets three times a day.
- To prevent relapses of ulcerative colitis or maintain remission of Crohn's disease: Take one tablet three times a day.
- Take your medicine at least 30 minutes before food.

More instructions can be found in Section [4. How do I take MESASAL?](#) in the full CMI.

5. What should I know while taking MESASAL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using MESASAL. • Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not take MESASAL to treat any other complaints unless your doctor tells you to. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• This medicine is not expected to affect your ability to drive a car or operate machinery. • Be careful before you drive or use any machines or tools until you know how MESASAL affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C. • Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while taking MESASAL?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of these less serious side effects and they worry you: headache, mild stomach pains, excessive gas in the stomach or bowel, increased number of bowel motions, diarrhoea, nausea, rash, common cold.

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: fever, muscle aches and pains, painful joints and chest pain, mild skin rash, itching or hives, severe upper stomach pain, numbness or weakness of the arms and legs, difficulty in breathing or swallowing, hayfever, strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears.

This is not a complete list of all possible side effects. 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.

MESASAL[®]

Active ingredient(s): *mesalazine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MESASAL. **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 MESASAL.**

Where to find information in this leaflet:

1. [Why am I taking MESASAL?](#)
2. [What should I know before I take MESASAL?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take MESASAL?](#)
5. [What should I know while taking MESASAL?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking MESASAL?

MESASAL contains the active ingredient mesalazine. MESASAL belongs to a group of medicines called salicylates. It works by suppressing inflammation in the large intestine.

MESASAL is used to treat acute inflammatory bowel disease and for regular treatment of Crohn's disease and ulcerative colitis.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

2. What should I know before I take MESASAL?

Warnings

Do not take MESASAL if:

- you are allergic to mesalazine, any other aspirin-line medicines, or any of the ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- Always check the ingredients to make sure you can use this medicine.
- you have severe kidney problems
- you have a bleeding disorder or if you are taking medicines to stop your blood from clotting
- you have a stomach or duodenal ulcer
- you are in the last weeks of pregnancy

- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- take any medicines for any other condition
- have or have had any of the following medical conditions:
 - o kidney or liver problems
 - o lung or breathing problems such as asthma
- have taken MESASAL or an aspirin-like medicine before and became unwell.
- have ever had an allergic reaction (such as rash) to MESASAL, sulfasalazine or aspirin-like medicines in the past.

Mesalazine may cause red-brown discolouration of urine after contact with sodium hypochlorite bleach (e.g. toilets cleaned with bleach). This is caused by a harmless chemical reaction between the active ingredient mesalazine and sodium hypochlorite.

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?

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with mesalazine treatment. If you experience any of these serious symptoms or additional ones described in Section 6. [Are there any side effects?](#) stop taking mesalazine and seek medical attention immediately.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears, contact your doctor immediately.

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

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

Do not breastfeed if you are taking this medicine.

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

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking MESASAL.

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 and MESASAL may interfere with each other. These include:

- anti-coagulant medicines such as warfarin, a medicine used to prevent blood clots
- glucocorticoids, medicines used to treat inflammation or swelling e.g. prednisolone
- medicines used to treat diabetes by lowering blood sugar levels (e.g. oral hypoglycaemics)
- medicines which contain probenecid and sulfinpyrazone
- medicines used to increase urine flow, such as spironolactone and furosemide
- medicines which contain rifampicin
- medicines used to suppress the immune system such as methotrexate, azathioprine or 6-mercaptopurine

These medicines may be affected by MESASAL or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I take MESASAL?

How much to take

- Take MESASAL as directed by your doctor or pharmacist.
- The usual dose of MESASAL for acute ulcerative colitis and Crohn's disease is two tablets, three times a day.
- To prevent relapses of ulcerative colitis or maintain remission of Crohn's disease, the usual dose is one tablet, three times a day.
- Follow the instructions provided and take MESASAL until your doctor tells you to stop.

When to take MESASAL

- **Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

- **Take your medicine at least 30 minutes before food.**

How to take MESASAL

- **Swallow the tablets whole with a glass of water.**
- **Do not crush or chew the tablets.**

How long to take MESASAL

- **Continue taking your medicine for as long as your doctor tells you to.**
- This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you forget to take MESASAL

MESASAL should be taken regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much MESASAL (overdose)

If you think that you or anyone else may have taken too much MESASAL, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 MESASAL?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MESASAL.**
- **Remind any doctor, dentist or pharmacist you visit that you are using MESASAL.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

Call your doctor straight away if you:

- **become pregnant while taking this medicine.**

Things you should not do

- Do not take MESASAL to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MESASAL affects you.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- **Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack, they may not keep well.

- **Keep your tablets in a cool dry place where the temperature stays below 25°C. Protect the tablets from light and moisture.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any side effects?

This medicine helps most people with inflammatory bowel disease, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
• headache • mild stomach pains • excessive gas in the stomach or bowel • increased number of bowel motions • diarrhoea • feeling sick (nausea) • itchy skin or rash • dizziness • common cold	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
• fever, muscle aches and pains, painful joints and chest pain (sometimes spreading to the neck and shoulders, and sometimes fever) • mild skin rash, itching or hives • severe upper stomach pain, often with nausea and vomiting • numbness or weakness of the arms and legs • wheezing, swelling of the limbs/ lips/ tongue/ mouth/ face/throat, difficulty in breathing or swallowing, hayfever, lumpy rash (hives) or fainting • serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN). They can present as 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, widespread rash, fever and enlarged lymph nodes. These serious skin rashes can be preceded by fever and flu-like symptoms. • strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull	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
(idiopathic intracranial hypertension)	

Other rare events, which have been reported with mesalazine, include:

- changes in kidney function and inflammation of the kidney
- changes in blood test results such as low white blood cell and/or platelet counts
- changes in liver function tests
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- changes relating to your heart
- allergic, inflammatory or other lung conditions
- shortness of breath, difficulty breathing, cough, wheezing, chest pain that worsens when breathing
- increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)
- reversible decrease in semen production (oligospermia)
- hair loss and the development of baldness (alopecia)
- severe diarrhoea and abdominal pain due to an allergic reaction to this medicine (pancolitis)

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.

Some side effects can only be found when your doctor does tests from time to time to check your progress.

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 MESASAL contains

Active ingredient (main ingredient)	mesalazine
Other ingredients (inactive ingredients)	calcium stearate colloidal anhydrous silica glycine iron oxide red iron oxide yellow

	macrogol 6000 methacrylic acid copolymer microcrystalline cellulose povidone purified talc sodium carbonate titanium dioxide triethyl citrate
Potential allergens	47.7 mg elemental sodium per enteric coated tablet

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

What MESASAL looks like

MESASAL is a round, biconvex and tan coloured enteric coated tablet. (AUST R 289132).

Who distributes MESASAL

Viatris Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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