

MESASAL[®]

mesalazine

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about MESASAL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MESASAL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MESASAL is used for

MESASAL contains the active ingredient mesalazine (5-aminosalicylic acid) which is used to treat:

- acute inflammatory bowel disease

MESASAL is used for regular treatment of:

- Crohn's disease
- ulcerative colitis

This medicine belongs to a group of medicines called salicylates.

It works by suppressing inflammation in the large intestine.

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.

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

Before you take MESASAL

When you must not take it

Do not take MESASAL if you have an allergy to:

- mesalazine
- any other aspirin-like medicines
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take MESASAL if you:

- have severe kidney problems
- have a bleeding disorder or if you are taking medicines to stop your blood from clotting
- have a stomach or duodenal ulcer
- are in the last weeks of pregnancy

Do not take this medicine if you are pregnant.

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

Do not breast-feed if you are taking this medicine.

Do not take this medicine after the expiry date printed on the pack 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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney or liver problems
- lung or breathing problems such as asthma

You must tell your doctor if:

- you have taken MESASAL or an aspirin-like medicine before and became unwell
- you have ever had an allergic reaction (such as rash) to MESASAL, sulfasalazine or aspirin-like medicines in the past

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 hypoglycemics)
- medicines which contain probenecid and sulphapyrazone
- medicines used to increase urine flow, such as spironolactone and frusemide
- 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.

How to take MESASAL

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.

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.

How to take it

Swallow the tablets whole with a glass of water.

Do not crush or chew the tablets.

When to take it

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 long to take it

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.

If you forget to take it

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 that 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 (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at

the nearest hospital, if you think that you or anyone else may have taken too much MESASAL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using MESASAL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MESASAL.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery until you know how MESASAL affects you.

Side-effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking MESASAL.

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the 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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

These could be symptoms of an allergic reaction.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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 that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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

After using MESASAL

Storage

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.

Do not store MESASAL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MESASAL tablets are round, biconvex and tan coloured.

Ingredients

MESASAL contains 250 mg of mesalazine as the active ingredient.

The enteric coated tablets also contain the following inactive ingredients:

- sodium carbonate
- glycine
- microcrystalline cellulose
- calcium stearate
- povidone
- colloidal silica anhydrous

The coating on the tablets contains:

- povidone
- titanium dioxide
- red iron oxide (CI77491)
- yellow iron oxide (CI77492)
- purified talc
- Macrogol 6000
- methacrylic acid
- triethyl citrate

MESASAL contains 47.7 mg elemental sodium per enteric coated tablet.

Distributor

MESASAL is distributed in Australia by:

Viatrix Pty Ltd

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

This leaflet was prepared in December 2022.

Australian registration numbers:

AUST R 289132

MESASAL® is a Viatrix company trade mark

mesasal_cmi\Dec22/00