

## MESASAL® TABLETS

Mesalazine

Enteric coated tablets

### Consumer Medicine Information

#### What is in this leaflet?

Please read this leaflet carefully before you take Mesasal.

This leaflet answers some common questions about Mesasal. It does not contain all of 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 expected benefits of you taking Mesasal against the risks this medicine could 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 want to read it again.

#### What is Mesasal used for?

Mesasal is used to treat acute inflammatory large bowel disease, which may include Crohn's colitis and ulcerative colitis.

Mesasal is used for regular treatment of Crohn's colitis and ulcerative colitis.

Mesasal belongs to a group of medicines called salicylates.

Mesasal is thought to work by suppressing inflammation in the large bowel.

Your doctor may have prescribed Mesasal for another reason.

There is no evidence that Mesasal is addictive.

#### Before you take Mesasal

##### *Do not take if:*

You must not take Mesasal if:

- **you have ever had an allergic reaction to mesalazine or aspirin-like medicines or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").**
- **you have a severe kidney problem.**
- **you have a bleeding disorder or if you are taking medicine to stop your blood clotting.**
- **you have a stomach or duodenal ulcer.**
- **you are in the last weeks of pregnancy.**
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering.**

##### *Tell your doctor if:*

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **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.**
- **you have kidney or liver problems.**
- **you are taking medicines which:**
  - **thin the blood or prolong bleeding time (anti-coagulants such as warfarin),**

- **treat diabetes by lowering blood sugar levels (oral hypoglycemics),**
- **contain probenecid and sulphapyrazone,**
- **increase urine flow (such as spironolactone and frusemide),**
- **contain rifampicin,**
- **contain methotrexate,**
- **contain azathioprine or 6-mercaptopurine**

- **you are taking any other medicines or have used other medicines until recently, including medicines you buy without a prescription.**
- **you are breastfeeding, pregnant or trying to become pregnant.**
- **you think your condition is getting worse.**

#### How do I take Mesasal?

##### *How much to take*

Take Mesasal as directed by your doctor or pharmacist.

##### *How to take it*

The usual dose of Mesasal for acute ulcerative colitis and Crohn's disease is two tablets three times daily.

To prevent relapses of ulcerative colitis or maintain remission of Crohn's disease, the usual dose is one tablet three times daily.

For some conditions, your doctor may prescribe a different dose.

Swallow the Mesasal tablets whole with plenty of fluid. Do not crush or chew the tablets.

It is best to take Mesasal tablets at least 30 minutes before food.

##### *How long to take it for*

**Keep taking your Mesasal for as long as your doctor tells you to.**

**Do not stop taking Mesasal, or change the dose without first checking with your doctor.**

##### *Use in children and elderly patients*

There is no specific information available to recommend the use of Mesasal in children.

#### What do I do if I take too much? (Overdose)

**Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken a large number of Mesasal, tablets all at once. Do this even if there are no signs of discomfort or poisoning.**

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

#### While you are taking Mesasal

##### *Things you must do*

**Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.**

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

**If you have just missed a dose, take the dose as soon as you remember and then go back to taking it as directed by your doctor.**

**If it is almost time for your next dose, skip the dose you missed and take your next dose at the normal time. Do not take a double dose to make up for the dose that you missed.**

**Tell your doctor, dentist or pharmacist you are taking Mesasal before starting any other medicines. This includes medicines that you buy without prescription as well as other medicines.**

If you become pregnant while you are taking Mesasal, tell your doctor.

##### *Things you must not do*

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

**Do not use Mesasal to treat any other complaints unless your doctor says to.**

**Do not stop taking Mesasal, or lower the dosage because you are feeling better, unless advised by your doctor.**

##### *Things to be careful of*

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

#### What are the side-effects?

**Check with your doctor as soon as possible if you are experiencing any side effects or allergic reactions due to taking Mesasal, even if the problem is not listed below.**

Like other medicines, Mesasal can cause some side-effects. If they occur, they are most likely to be mild and may disappear without stopping Mesasal. However, some may be serious and need medical attention.

##### *Mild effects*

Tell your doctor or pharmacist if you notice any of the following that are troublesome or ongoing:

- **headache.**
- **mild stomach pains.**
- **increased numbers of bowel motions.**
- **feeling sick (nausea).**
- **itchy skin or rash.**

##### *More serious effects*

**Tell your doctor immediately if you notice any of the following:**

- **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.**

Other rare events that have been reported with Mesasal include:

- changes in kidney function and inflammation of the kidney.
- changes in blood test results such as low white blood cell count and low platelet count.
- 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.
- worsening of your inflammatory large bowel disease symptoms.
- Decreased sperm count and impaired sperm motility, which may affect male fertility, have been reported with mesalazine. This effect may be reversible when treatment is discontinued. If you are concerned about this, speak with your doctor.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

**Do not be alarmed by this list of possible side-effects. You may not experience any of them.**

---

#### How do I store Mesasal?

**Keep this medicine where children cannot reach it, such as in a locked cupboard.**

**Keep Mesasal tablets in a cool, dry place where it stays below 25°C. Protect from light and moisture. Do not leave in a car, on a window sill or in the bathroom.**

**Keep Mesasal tablets in the original blister pack until time to take.**

**Return any unused or expired medicine to your pharmacist.**

---

#### Product description

##### *What Mesasal looks like*

**Mesasal looks like round, tan, enteric coated tablets containing 250mg of mesalazine in blister platforms of 20 tablets in packs of 100.**

##### *Ingredients*

Mesasal contains the active ingredient mesalazine.

Mesasal tablets also contains the following inactive ingredients: sodium carbonate, glycine, microcrystalline cellulose, calcium stearate, povidone and 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 and Triethyl Citrate.

##### *Sponsor*

Your Mesasal is supplied by:  
Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos Street  
St Leonards NSW 2065  
Australia.

##### *Where to go for further information*

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its

treatment from patient information groups and product specific organisations.

This leaflet was prepared in August 2017  
The information provided applies only to: Mesasal®.

Mesasal® is a registered trade mark of Aspen Global Incorporated.

Mesasal: AUST R 289132

© 2017 Aspen Global Incorporated