PENTASA® sachets

Consumer Medicine Information (CMI) summary

The full CMI (see from next page) has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking PENTASA?

PENTASA contains the active ingredient, mesalazine. PENTASA is taken to treat Crohn's disease and ulcerative colitis: diseases associated with inflammation, ulcers and sores in the bowel causing bleeding, stomach pain, and diarrhoea.

For more information, see Section 1. Why am I taking PENTASA? in the full CMI (see from next page), starting from page 2.

2. What should I know before I take PENTASA?

Do not take PENTASA if you have ever had an allergic reaction to mesalazine or any of the ingredients listed at the end of the CMI (Section 7 Product details).

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 PENTASA? in the full CMI, starting from page 2.

3. What if I am taking other medicines?

Care may be needed when you are also taking other medicines.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI, starting from page 2.

4. How do I take PENTASA?

- Tear or cut to open the sachet along the dotted line.
- Empty the content of the sachet (granules) onto the tongue and wash down with water or juice to swallow without chewing or crushing the granules.
- Alternatively, mix the entire content of the sachet (granules) with yoghurt and consume immediately without chewing or crushing the granules. More instructions can be found in Section 4. How do I take PENTASA? in the full CMI, starting from page 2.

5. What should I know while taking PENTASA?

Things you should do	• Tell any doctor, dentist or pharmacist you visit that you are taking PENTASA • Have all blood tests recommended by your doctor • **If you become pregnant while taking this medicine, tell your doctor immediately.**
Things you should not do	• Do not stop taking this medicine or change the dosage without checking with your doctor • Do not take PENTASA to treat any other complaints unless your doctor tells you to • Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• PENTASA is not expected to affect your

	ability to drive a car or operate machinery.
Looking after your medicine	• Keep your PENTASA in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while taking PENTASA? in the full CMI, starting from page 2.

6. Are there any side effects?

All medicines can have side effects. Side effects reported from PENTASA can be minor and temporary. However, some side effects may need medical attention.

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, starting from page 2.

PENTASA® sachets

Active ingredient: *mesalazine*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking PENTASA.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking PENTASA.

Where to find information in this leaflet:

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

1. Why am I taking PENTASA?

PENTASA contains the active ingredient, mesalazine. PENTASA is an anti-inflammatory agent, similar to aspirin, and is thought to work by reducing inflammation in the bowel.

PENTASA is taken to treat Crohn's disease and ulcerative colitis, diseases associated with inflammation, ulcers and sores in the bowel causing bleeding, stomach pain, and diarrhoea.

2. What should I know before I take PENTASA?

Warnings

Do not take PENTASA if:

- you are allergic to mesalazine, sulfasalazine, aspirin-like medicines or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine
- you have a severe kidney or liver problem
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Your doctor should make you aware of the signs and symptoms that may indicate allergic reaction when taking PENTASA.

Check with your doctor if you:

- have a known allergy to PENTASA, sulfasalazine or aspirin-like medicines, or any of the ingredients listed at the end of this leaflet
- take any medicines for any other condition
- have a kidney or liver problem

- have a bleeding disorder
- have a history of asthma.

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.

Your doctor can discuss with you the risks and benefits involved with taking PENTASA. PENTASA should be taken with caution during pregnancy and breast-feeding and only if the potential benefits outweigh the possible risks in the opinion of the doctor. The underlying condition itself (inflammatory bowel disease) may increase risks for the pregnancy outcome.

Children

Do not give PENTASA to a child 12 years old or under.

The safety and effectiveness of PENTASA in this age group have not been established.

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.

There is no information available on interactions between PENTASA and other medicines. However, mesalazine belongs to a group of medicines called salicylates that may interfere with some medicines.

Medicines that may have their effects increased if used with PENTASA include:

- anti-coagulants which are used to thin blood or stop blood clots (e.g. warfarin). When PENTASA is used with these medicines, it may increase the medicine's effects on thinning your blood
- sulphonylureas which are used to lower blood sugar and treat diabetes (e.g. glibenclamide, glipizide). When PENTASA is used with these medicines, it may increase the medicine's effect on lowering your blood sugar
- methotrexate which is used to treat some kinds of cancers, some skin conditions, and rheumatoid arthritis. When PENTASA is used with this medicine, it may increase the possibility of the medicine producing toxic effects on your body
- glucocorticoids which are used to treat inflammation, swelling or allergies (e.g. prednisolone). When PENTASA is used with these medicines, it may

increase the undesirable gastric effects caused by these medicines.

Medicines that may have their effects decreased if used with PENTASA include:

- probenicid or sulfinpyrazone which are used to treat gout. When PENTASA is used with these medicines it may decrease the effectiveness of the medicine
- spirinolactone or furosemide, which are used to increase the amount of urine produced and to lower blood pressure. When PENTASA is used with these medicines it may decrease the effectiveness of the medicine
- rifampicin which is used to treat tuberculosis. When PENTASA is used with this medicine it may decrease the effectiveness of the medicine.

Medicines that may have a greater likelihood of reducing bone marrow activity if used with PENTASA include:

- azathioprine which is used to suppress the immune system
- mercaptopurine and tioguanine, used to treat leukaemia.

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

4. How do I take PENTASA?

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.

How much to take

- Recommended doses for various conditions are presented below.
- Your doctor will prescribe a dose based on your individual needs, and this may differ from these recommendations.
- Follow the instructions provided by your doctor and use PENTASA until your doctor tells you to stop.

Ulcerative Colitis

- For active disease (flare-up of symptoms) for ulcerative colitis, take up to 4 g PENTASA once a day or in divided doses.
- For maintenance (during remission) for ulcerative colitis, take up to 2 g PENTASA once a day or in divided doses.

Crohn's disease

- For active disease (flare-up of symptoms) for Crohn's disease, take up to 4 g PENTASA daily in divided doses.
- For maintenance (during remission) for Crohn's disease, take up to 4 g PENTASA daily in divided doses.

When to take PENTASA

- Take your medicine at the same time each day. This will help you remember when to take it.
- You can take PENTASA with or without food.
- Continue taking your medicine for as long as your doctor tells you.

How to take PENTASA

- Tear or cut to open the sachet along the dotted line.
- Empty the content of the sachet (granules) onto the tongue and wash down with water or juice to swallow without chewing or crushing the granules.

Alternatively, mix the entire content of the sachet (granules) with yoghurt and consume immediately without chewing or crushing the granules.

Scan the QR code with your smartphone or tablet to access a video on administering PENTASA® Enema. Select the PENTASA® link on the website, enter the AUST R number from the PENTASA® box or Section 7 of this document, and scroll to resources. Alternatively, visit patients.ferring.com.au/gastroenterology/
Access available only within Australia.

If you forget to take PENTASA

PENTASA 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.

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

- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take PENTASA, ask your pharmacist for some hints.

If you take too much PENTASA

If you think that you have taken too much PENTASA, 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 Accident and 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 taking PENTASA?

Things you should do

Have all blood tests recommended by your doctor

- PENTASA may cause kidney, liver or blood problems in a few people. You should have regular blood tests to check your kidney function.
- Kidney stones may develop while taking PENTASA. Symptoms may include pain in the sides of the abdomen and blood in the urine.
- Take care to drink plenty of fluids while you are being treated with PENTASA.

If you are going to have surgery

- Tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

Remind any doctor, dentist or pharmacist you visit that you are taking PENTASA.

Things you should not do

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

Driving or using machines

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

Looking after your medicine

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

- Keep your PENTASA in the packaging until it is time to take your next dose.
- If you take PENTASA out of the packaging it may not keep well.
- Keep your PENTASA in a cool dry place (temperature below 25°C), away from moisture, heat or sunlight.

Do not store it:

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

Keep it where children cannot reach it.

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?

All medicines can have side effects. Most side effects reported by patients after taking PENTASA (mesalazine) are minor and temporary. However, some side effects may need medical attention.

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

Less serious side effects

Side effects	What to do
Common side effects (affect more than 1 in 100 users): • headache • diarrhoea • abdominal or stomach pain • nausea • vomiting	**These side effects are not usually serious but can become serious** **Speak to your doctor if you have any of**

Side effects	What to do
• flatulence (stomach discomfort or fullness, relieved by passing wind) • mild skin rash **Rare side effects (affect less than 1 in 1,000 users):** • dizziness • photosensitivity (especially if you have eczema or dermatitis) **Very rare side effects (affect less than 1 in 10,000 users):** • changes in blood counts e.g. a decrease in the number of red/white blood cells, and/or platelets • difficulty breathing, coughing (allergic and fibrotic lung reactions) • changes in liver function e.g. raised liver enzymes • hair loss (reversible)	**these side effects**

Side effects	What to do
• painful or swollen joints (arthralgia) • muscle aches and pains (myalgia) • disease affecting the skin, joints and kidneys with symptoms such as joint pain, fever and skin rash (lupus erythematosus-like reactions) • low sperm count (reversible). • drug fever e.g. fever-like symptoms such as chills and aches **Frequency unknown:** • kidney stones	

Serious side effects

Serious side effects	What to do
Rare side effects (affect less than 1 in 1,000 users): • chest pain, irregular heartbeat, shortness of	**Call your doctor straight away, if you notice any of these serious side effects**

Serious side effects	What to do
breath (myocarditis and pericarditis) • inflammation of the pancreas e.g. severe upper stomach pain, nausea and vomiting (increased amylase, acute pancreatitis) **Very rare side effects (affect less than 1 in 10,000 users):** • bruising easily, unusual bleeding (e.g. nosebleeds), signs of infection such as fever, chills, sore throat and mouth ulcers (aplastic anemia or agranulocytosis) • numbness, tingling or weakness of the arms and legs (peripheral neuropathy) • worsening of your condition e.g. severe diarrhea, bloody stools (pancolitis) • liver disease e.g. yellowing of the	

Serious side effects	What to do
skin or eyes, urine discolouration • kidney disease e.g. changes in urine output and/or discolouration, blood in urine and/or swelling **Frequency unknown:** • increased pressure in the brain, strong or frequent headaches, changes in vision, or ringing in the ears (idiopathic intracranial hypertension)	
Allergic reaction (very rare - affect less than 1 in 10,000 users): • Sudden signs of allergic reactions such as rash, itching or hives, shortness of breath, wheezing, coughing, or swelling of limbs, face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing	**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
Severe Cutaneous Adverse Reactions (SCAR) such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (very rare - affect less than 1 in 10,000 users); Stevens-Johnson Syndrome (SJS) /Toxic epidermal necrolysis (TEN) (frequency unknown): • Nausea, severe stomach cramps and/or pain, bloody diarrhoea, fever, facial swelling, severe headache and skin rash with severe blisters and bleeding of the eyes, mouth, lips, nose and genitals.	

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 PENTASA contains

Active ingredient **(main ingredient)**	mesalazine
Other ingredients **(inactive ingredients)**	povidone ethylcellulose

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

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

What PENTASA looks like

PENTASA Sachets contain short and cylindrical (or tube) shaped granules that are white-grey to pale white brown in colour.

PENTASA 1 g Sachets are supplied in packs of 30, 100 and 120. (AUST R 161063)

PENTASA 2 g Sachets are supplied in packs of 15 and 60. (AUST R 161064)

PENTASA 4 g Sachets are supplied in packs of 8 and 30. (AUST R 216259)

Not all pack sizes are distributed in Australia.

Who distributes PENTASA

PENTASA Sachets are supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble, NSW 2073, Australia.

PENTASA® is a registered trademark of Ferring B.V.

® = Registered trademark

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