

PENTASA® tablets

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.

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?

- Swallow the tablets whole without chewing or crushing. You can also place the tablets in 50mL of cold water, stir rapidly and drink immediately
- Do not cut, crush or chew the tablets. 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	<ul style="list-style-type: none">• Tell any doctor, dentist or pharmacist you visit that you are taking PENTASA• Have all blood tests recommended by your doctor• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine• If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or lower 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	<ul style="list-style-type: none">• PENTASA is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• 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® tablets

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 or about why this medicine has been prescribed for you.

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, 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.

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.

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?](#)

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

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.

If you have not told your doctor about any of the above, tell him/her before you start using PENTASA®.

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:

- probenidic or sulfapyrazone 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.

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

4. How do I take PENTASA?

This medicine can help 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.
- If you do not understand the instructions on the packaging, ask your doctor or pharmacist for help.

Adults:

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.

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

Children:

A child's dose will be individualized based on their body weight.

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

- Swallow the tablets whole without chewing or crushing. You can also place the tablets in 50mL of cold water, stir rapidly and drink immediately.
- Do not cut, crush or chew the tablets.

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 telephone your doctor or the Poisons Information Centre (telephone 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much PENTASA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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 lower 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.

Heat and dampness can damage 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.

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?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PENTASA®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. 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

Less serious side effects	What to do
<p>Common side effects (affect more than 1 in 100 users)</p> <p>Nervous system related:</p> <ul style="list-style-type: none"> • headache <p>Stomach and intestine related:</p> <ul style="list-style-type: none"> • diarrhoea • abdominal or stomach pain • flatulence (stomach discomfort or fullness, relieved by-passing wind) • nausea (feeling sick) • vomiting <p>Skin related:</p> <ul style="list-style-type: none"> • mild skin rash <p>Rare side effects (affect less than 1 in 1000 users)</p> <ul style="list-style-type: none"> • dizziness • photosensitivity (especially if you have eczema or dermatitis) <p>Very rare side effects (affect less than 1 in 10,000 users)</p> <p>Blood and lymph system related</p> <ul style="list-style-type: none"> • changes in blood counts e.g. a decrease in the number of red/white blood cells, and/or platelets <p>Breathing and chest related</p> <ul style="list-style-type: none"> • difficulty breathing, coughing (allergic and fibrotic lung reactions) <p>Liver and gallbladder related:</p> <ul style="list-style-type: none"> • changes in liver function e.g. raised liver enzymes <p>Skin related</p>	<p>These side effects are not usually serious but can become serious. Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> hair loss (reversible) <p>Bone, muscle and tissue related</p> <ul style="list-style-type: none"> painful or swollen joints (arthralgia) muscle aches and pains (myalgia) lupus erythematosus-like reactions (a disease affecting the skin, joints and kidneys with symptoms such as joint pain, fever and skin rash) <p>Reproductive system related</p> <ul style="list-style-type: none"> low sperm count (reversible) <p>General and administration site related:</p> <ul style="list-style-type: none"> drug fever e.g. fever-like symptoms such as chills and aches <p>Frequency unknown</p> <ul style="list-style-type: none"> kidney stones 	
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Serious side effects	What to do
<p>urine discolouration, blood in urine and/or swelling in ankles or feet</p> <p>Liver and gallbladder related:</p> <ul style="list-style-type: none"> yellowing of the skin or eyes, dark coloured urine <p>Skin related:</p> <ul style="list-style-type: none"> red lesion or rash (erythema multiforme or dermatitis allergic) <p>Condition related:</p> <ul style="list-style-type: none"> worsening of your condition e.g. severe diarrhea, bloody stools (pancolitis) <p>Frequency unknown:</p> <ul style="list-style-type: none"> Increased pressure in the brain, strong or frequent headaches, changes in vision, or ringing in the ears (idiopathic intracranial hypertension) 	

Serious side effects

Serious side effects	What to do
<p>Rare side effects (affects less than 1 in 1000 users)</p> <p>Breathing and chest related:</p> <ul style="list-style-type: none"> chest pain, irregular heartbeats, shortness of breath and/or pain behind the breast bone sometimes spreading to the neck and shoulders, or with fever (myocarditis and pericarditis) <p>Stomach and intestine related:</p> <ul style="list-style-type: none"> severe upper stomach pain, nausea and vomiting <p>Very rare side effects (affect less than 1 in 10000 users)</p> <p>Nervous system related:</p> <ul style="list-style-type: none"> numbness, tingling or weakness of the arms and legs (peripheral neuropathy) <p>Blood and lymph system related:</p> <ul style="list-style-type: none"> bruising easily, unusual bleeding (e.g. nosebleeds), signs of infection such as fever, chills, sore throat and mouth ulcers (aplastic anemia or agranulocytosis) <p>Kidney and urinary related:</p> <ul style="list-style-type: none"> changes in kidney function/kidney disease, e.g. changes in urine output and/or 	<p>Call your doctor straight away, if you notice any of these serious side effects.</p>

<p>Allergic reaction (very rare – affect less than 1 in 10000 users)</p> <p>Immune system related:</p> <ul style="list-style-type: none"> 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 Severe Cutaneous Adverse Reactions (SCAR) such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) <p>Frequency unknown</p> <ul style="list-style-type: none"> Stevens-Johnson Syndrome (SJS)/ Toxic epidermal necrolysis (TEN) nausea, severe stomach cramps and/or pain, bloody diarrhoea, fever, severe headache and skin rash with severe blisters and bleeding of the eyes, mouth, lips, nose and genitals 	<p>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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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.

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)	magnesium stearate talc povidone ethylcellulose microcrystalline cellulose

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 500mg prolonged release tablets are white-grey to pale brown, speckled round tablets with breakmark and marked: '500 mg' on one side, and 'PENTASA' on the other side. They are supplied in blister packs of 100 tablets.

Each tablet is protected in an aluminium foil blister.

Who distributes PENTASA

PENTASA Tablets are supplied in New Zealand by:

Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington
Auckland 1060

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® = Registered trademark

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