

PENTASA[®]

Mesalazine

Prolonged release tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PENTASA[®].

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

Please read this leaflet before you start using PENTASA[®].

All medicines have risks and benefits. Your doctor has weighed the risks of you using PENTASA[®] against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What PENTASA[®] is used for

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

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

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.

There is no evidence that PENTASA[®] is addictive.

It is available only with a doctor's prescription.

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

Before you take PENTASA[®]

When you must not take it

Do not take PENTASA[®] if you have an allergy to:

- **any medicine containing mesalazine or 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 PENTASA[®] if you have a severe kidney or liver problem.

Do not take PENTASA[®] 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.

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:

- a known allergy to PENTASA[®], sulphasalazine or aspirin-like medicines, or any of the ingredients listed at the end of this leaflet
- a kidney or liver problem
- a bleeding disorder
- a history of asthma

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. PENTASA[®] should be used with caution during pregnancy and lactation and only if the potential benefits outweigh the possible risks in the opinion of the doctor.

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

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you get 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, 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.
- glucocorticoids, used to treat inflammation, swelling or allergies (e.g. prednisolone). When PENTASA is used with these medicines, it may increase the undesirable effects caused by these medicines.
- sulphonylureas, 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 glucose.
- methotrexate, used to treat some kinds of cancers and arthritis. When PENTASA is used with this medicine, it may increase the possibility of the medicine producing toxic effects on your body.

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

- probenecid or sulfinpyrazone, used to treat gout or other conditions. When PENTASA is used with these medicines it may decrease the effectiveness of the medicine.
- spirinolactone or frusemide, 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, 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, used to suppress the immune system
- mercaptopurine, used to treat leukaemia

Ask your doctor or pharmacist if you are unsure about taking any of these medicines.

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

How to take PENTASA®

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 packaging, ask your doctor or pharmacist for help.

How much to take

Adults:

Ulcerative Colitis

For active ulcerative colitis (flare-up of symptoms), take up to 4g PENTASA® once daily or in divided doses.

For maintenance (during remission) of ulcerative colitis, take up to 2g PENTASA® once a day or in divided doses.

Crohn's Disease

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

For maintenance (during remission) of Crohn's disease, take up to 4g PENTASA® daily in divided doses.

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

Children:

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

How to take it

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.

When to take it

Take your medicine the same time each day. This will help you remember when to take it.

You can take Pentasa with or without food.

How long to take it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep using 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 PENTASA® as you would normally.

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 use too much (overdose)

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.

While you are taking PENTASA®

Things you must do

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

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.

Tell any other doctors, dentists, and pharmacists

who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

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

Things you must not do

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.

Do not stop using your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Side effects

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

This medicine helps most people 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 experience 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
- diarrhoea
- abdominal or stomach pain
- nausea (feeling sick)
- vomiting

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

Tell your doctor as soon as possible if you notice any of the following:

- bruising easily, unusual bleeding (e.g. nosebleeds), or signs of infection such as fever, chills, sore throat and mouth ulcers
- muscle aches and pains
- painful joints
- severe upper stomach pain, nausea and vomiting
- chest pain, sometimes spreading to the neck and shoulders, or with fever
- mild skin rash, hives or itching
- numbness, tingling or weakness of the arms and legs
- yellowing of the skin or eyes, dark coloured urine
- worsening of your condition

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

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

- 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 stomach cramps and/or pain, bloody diarrhoea, fever, severe headache and skin rash
- rash with severe blisters and bleeding of the eyes, mouth, lips, nose and genitals e.g. erythema multiforme or Stevens-Johnson Syndrome (SJS)/ Toxic epidermal necrolysis (TEN)

The above list includes very serious side effects, which may need urgent medical attention or hospitalisation. These side effects are very rare.

Other rare side effects that have been reported with PENTASA[®] include:

- changes in kidney function
- changes in liver function e.g. raised liver enzymes
- changes in the blood
- hair loss
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.
- Low sperm count (this is reversible)

As a precaution, your doctor may do blood tests to check if there are any changes in your blood, kidney, reproductive or liver function.

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After taking PENTASA[®]

Storage

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 where the temperature stays below 25°C, away from moisture, heat or sunlight

Do not store PENTASA[®] 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 damage some medicines.

Keep PENTASA[®] 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 PENTASA[®] 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

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.

Ingredients

PENTASA[®] tablets contain 500mg mesalazine as the active ingredient, as well as the following inactive ingredients:

- magnesium stearate
- talc
- povidone
- ethylcellulose
- microcrystalline cellulose

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

Distributor

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

This leaflet was prepared in July 2021
(CCDS v 17)