

PENTASA®

Prolonged Release Tablets

mesalazine

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.

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.

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, sulfasalazine 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 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.

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 the following types of medicines:

- anti-coagulants, used to thin blood or stop blood clots (eg warfarin)
- glucocorticoids, used to treat inflammation, swelling or allergies (eg prednisolone)
- sulphonylureas, used to lower blood sugar and treat diabetes (eg glibenclamide, glipizide)
- methotrexate, used to treat some kinds of cancers and arthritis
- probenecid or sulfinpyrazone, used to treat gout
- spirinolactone or frusemide, used to increase the amount of urine produced, and to lower blood pressure
- rifampicin, used to treat tuberculosis
- azathioprine, used to suppress the immune system
- mercaptopurine and thioguanine, 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, take up to 4 g PENTASA once a day or in divided doses.

For long term treatment of ulcerative colitis, take up to 2 g PENTASA once a day or in divided doses.

Crohn's Disease

For active Crohn's disease, take up to 4 g PENTASA daily in divided doses.

For long term treatment of Crohn's disease, take up to 4 g PENTASA daily in divided doses.

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

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 take too much (overdose)

Immediately telephone your doctor or the 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 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.

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.

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
- flatulence (stomach discomfort or fullness, relieved by passing wind)
- nausea (feeling sick)

- vomiting
- mild skin rash.

The above list includes the more common side effects of your medicine (affecting between 1 in 10 and 1 in 100 patients). They are usually mild and short-lived.

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

- dizziness
- bruising easily, unusual bleeding (e.g. nosebleeds), signs of infection such as fever, chills, sore throat and mouth ulcers
- muscle aches and pains
- painful or swollen joints
- severe upper stomach pain, nausea and vomiting
- changes in kidney function/kidney disease, and or urine discolouration
- numbness, tingling or weakness of the arms and legs
- yellowing of the skin or eyes, dark coloured urine
- hair loss (this is reversible)
- worsening of your condition.
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

The above list includes serious side effects which may require medical attention. Serious side effects are usually rare or very rare (affecting less than 1 in 1,000 patients).

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)

- lupus erythematosus-like reactions (a disease affecting the skin, joints and kidneys with symptoms such as joint pain, fever and skin rash)
- chest pain and/or pain behind the breast bone sometimes spreading to the neck and shoulders, or with fever.

The above list includes very serious side effects, which may need urgent medical attention or hospitalisation. These side effects are usually rare or very rare (affecting less than 1 in 1,000 patients).

Other very 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 e.g. a decrease in the number of red/white blood cells, and/or platelets
- 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 or liver function.

Very rare side effects occur in less than 1 in 10,000 patients.

Kidney stones may develop while taking PENTASA. Symptoms may include pain in the sides of the abdomen and blood in the urine.

The frequency of this side effect is not known.

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.

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 0.5 g 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 packs of 30 and 100 tablets.

PENTASA 1 g prolonged release tablets are white-grey to pale brown speckled oval tablets with 'PENTASA' marked on both sides. They are supplied in blister packs of 20 and 60 tablets. Each tablet is protected in an aluminium foil blister.

Not all pack sizes are being distributed in Australia.

Ingredients

PENTASA Tablets contain 0.5 g and 1 g 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.

Sponsor

PENTASA Tablets are supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street
Pymble, NSW 2073, Australia.

AUST R 99139 - PENTASA
mesalazine 0.5 g prolonged release
tablet blister pack

AUST R 164142 - PENTASA
mesalazine 1 g prolonged release
tablet blister pack

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® = Registered trademark



By scanning the QR code with your smart phone or tablet, you can access a video on how to administer PENTASA® Tablets. Alternative access via www.myibd.com.au
Access available only within Australia.