

PENTASA® Prolonged Release Tablets

Mesalazine 500mg and 1g

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1. What PENTASA® is used for

PENTASA® Prolonged Release Tablets are used to treat mild to moderate ulcerative colitis (an inflammation condition of the gut) and Crohn's disease (a condition that causes inflammation of the wall of the gut. Any part of the gut can be affected).

2. How PENTASA® works

PENTASA® contains the active ingredient mesalazine. The prolonged release tablets release the active ingredient slowly which then acts locally to reduce the inflammation and help relieve or stop the pain.

3. Before you use PENTASA®

When you must not use it
DO NOT take PENTASA®

- If you are allergic to mesalazine, other salicylic acid or its derivatives or to any of the other ingredients of PENTASA®.
- If you have severe liver and/or kidney impairment.

If this applies to you, do not take PENTASA® and tell your doctor immediately.

Before you start to use it

Warning and precautions

- Tell your doctor or pharmacist if you have or have had any of the following conditions:
 - Intolerant or hypersensitive to sulphasalazine
 - With impaired liver function

- With kidney impairment
- With lung disease, in particular asthma.
- Suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash.
- 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.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section Side effects.

Mesalazine-induced cardiac hypersensitivity reactions (myo- and pericarditis) have been reported rarely. Serious blood dyscrasias have been reported very rarely with mesalazine. Blood test for differential blood count is recommended prior to and during treatment, at the discretion of the treating physician.

Concomitant treatment with mesalazine can increase the risk of blood dyscrasia in patients receiving azathioprine, or 6-mercaptopurine or thioguanine. Treatment should be discontinued on suspicion or evidence of these adverse reactions.

As a guideline, follow-up tests are recommended 14 days after commencement of treatment, then a further two to three tests at intervals of 4 weeks. If the findings are normal, follow-up tests should be carried out every three months. If additional symptoms occur, these tests should be performed immediately.

- If any of these applies to you, talk to your doctor or pharmacist before taking PENTASA®.

Children and adolescents

Do not give this medicine to children.

There is only limited documentation for an effect in children (age 6-18 years). It is generally recommended that half the adult dose may be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg.

Taking other medicines

Other medicines and PENTASA®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking any of the following:

- azathioprine (used after transplantations or to treat auto-immune diseases)
- 6-mercaptopurine or thioguanine (chemotherapy, used to treat leukemia)
- certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is limited experience with the use of mesalazine during pregnancy and breast-feeding. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn

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develops diarrhoea, breast-feeding should be discontinued.

4. How to use PENTASA®

Always use PENTASA® exactly as your doctor has told you. You should check with your doctor if you are not sure.

How much to use

Ulcerative colitis

Treatment of active disease:

Adults: Individual dosage, up to 4g given once daily or in divided doses.

Children 6 years of age and older: To be determined individually, starting with 30-50 mg/kg/day in divided doses. Maximum dose: 75 mg/kg/day in divided doses. The total dose should not exceed 4 g/day (maximum adult dose).

Maintenance treatment:

Adults: Individual dosage.

Recommended dosage, 1.5g to 2g mesalazine once daily. Can also be taken in divided doses.

Children 6 years of age and older: To be determined individually, starting with 15-30 mg/kg/day in divided doses. The total dose should not exceed 2 g/day (recommended adult dose).

Crohn's disease

Treatment of active disease:

Adults: Individual dosage, up to 4g daily in divided doses.

Children 6 years of age and older: To be determined individually, starting with 30-50 mg/kg/day in divided doses. Maximum dose: 75 mg/kg/day in divided doses. The total dose should not exceed 4 g/day (maximum adult dose).

Maintenance treatment:

Adults: Individual dosage, up to 4g daily in divided doses.

Children 6 years of age and older: To be determined individually, starting with 15-30 mg/kg/day in divided doses. The total dose should not exceed 4 g/day (recommended adult dose).

PENTASA® tablets must not be chewed. To facilitate swallowing, the

tablets may be dispersed in 50 ml of cold water. Stir and drink immediately.

When to use it

Always use PENTASA® exactly as your doctor has told you. If you are not sure, check with your doctor.

How long to use it

You should continue to use PENTASA® for as long as your doctor tells you to.

If you forget to use it

It is important not to miss a dose of PENTASA®. If you do miss a dose, take it as soon as you can, unless it is nearly time for your next dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

If you accidentally take more than the recommended dose of PENTASA® you may be at increased risk of experiencing possible side effects with this medicine.

Contact your doctor or nearest emergency department immediately for advice.

5. While you are using it

Things you must do

Take your medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Tell all the doctors, dentists and pharmacists treating you that you are taking PENTASA®.

Things you must not do

Do not chew the tablet.

Do not suddenly change the dose or stop taking PENTASA® unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give PENTASA® to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Always consult your doctor or pharmacist if PENTASA® can be taken together with other medication.

Driving and using machines

If PENTASA® make you feel dizzy or tired, do not drive or use machines and contact your doctor immediately.

6. Side effects

Like all medicines, PENTASA® can cause side effects, although not everyone gets them.

Stop using mesalazine and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, **widespread rash, fever and enlarged lymph nodes**. These serious skin rashes can be preceded by fever and flu-like symptoms.

The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)

- Headache
- Diarrhoea
- Abdominal pain
- Nausea
- Vomiting
- Flatulence (passing wind)
- Rash

Rare (may affect up to 1 in 1000 people)

- Dizziness
- Inflammation of some areas of the heart (myocarditis and pericarditis) which can cause shortness of breath and chest pain or palpitations (rapid or irregular heartbeat)

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- Inflammation of the pancreas (symptoms include back and/or stomach pain).
- Increased amylase (enzyme that helps digest carbohydrates)
- Itchy eruption and exaggerated sunburn on patches of sun-exposed skin (photosensitivity)

Very rare (may affect up to 1 in 10000 people)

- Anaemia and other blood diseases (decrease in the numbers of certain blood cells, which can cause unexplained bleeding, bruising, fever or sore throat)
- Allergic reaction (inflammation) which can affect different parts of the body such as joints, skin, kidneys, heart etc. (symptoms include painful joints, fatigue, fever, abnormal or unexplained bleeding (e.g. nose bleeds), bruising, purple discoloration of the skin (including severe skin erosions and severe blistering that may affect the skin as the protective barrier of the body))
- Peripheral neuropathy (a condition affecting the nerves of the hands and feet). Symptoms include tingling and numbness.
- Allergic and fibrotic lung reactions, inflammation of the lining of the lungs or lung scarring (symptoms include coughing, bronchospasm, chest discomfort or pain on breathing, breathing difficulties, bloody and/or excessive phlegm)
- Pancolitis (a kind of inflammatory bowel disorder (IBD) that affects the entire internal lining of the large bowel)
- Liver disorders (symptoms include jaundice (yellowing of the skin and/or eyes) and/or pale faeces)
- Hair loss (reversible)
- Muscle or joint pain
- kidney disorders (symptoms include blood in the urine, and/or oedema (swelling due to build-up of fluid))

- Semen with a low concentration of sperm (oligospermia) in men (reversible)
- Drug Fever

Not known (frequency cannot be estimated from the available data)

- kidney stones and associated kidney pain (see also section **Before you use PENTASA®**)
- [Change in urine colour](#)

It is important to note that several of these disorders can also be attributed to the inflammatory bowel disease itself.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

By reporting side effects you can help provide more information on the safety of this medicine.

7. Storage and Disposal of PENTASA®

Storage

Store below 30°C in the original package, as the product is sensitive to light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

8. Product Description

What it looks like

500mg: White-grey to pale brown, speckled round tablets. Breakmark and embossing: 500 mg on one side, PENTASA on the other side.

1g: White-grey to pale brown, speckled, oval tablets. Embossing on both sides: PENTASA.

Aluminum blisters. The top foil consists of an aluminum foil with heat-seal lacquer on the inner side and a lacquer on the outer side. The bottom foil consists of an aluminum foil with adhesive and PVC-film on the inner side and primer, adhesive and polyamide film on the outer side. Each blister foil contains 10 tablets.

500mg: 100 tablets
1g: 60 tablets

Ingredient

-Active Ingredient
Mesalazine.

-Other ingredients

Magnesium stearate, talc, ethylcellulose, povidone, microcrystalline cellulose.

MAL number

500mg: MAL19940439AZ
1g: MAL15045066AZ

9. Manufacturer and Product Registration Holder

Manufacturer

Ferring International Center SA
Chemin de la Vergognausaz 50
CH-1162 St. Prex
Switzerland

Product Registration Holder

Ferring Sdn Bhd
21-6, Block B, Jaya One,

PENTASA[®] Prolonged Release Tablets

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