

PENTASA® 500 mg Slow-Release Tablets

For use in adults and children from the age of 6 years.
Active ingredient: mesalazine.



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

1. WHAT PENTASA® 500mg SLOW-RELEASE TABLETS ARE AND WHAT THEY ARE USED FOR

PENTASA® 500mg slow-release tablets are intestinal therapeutic agents. PENTASA® 500mg slow-release tablets are used in:

- Acute treatment of ulcerative colitis (inflammation of the large intestine with ulceration) and prophyllaxis for relapse.
- Treatment for symptomatic improvement in cases of active Crohn's disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PENTASA® 500mg SLOW-RELEASE TABLETS

Do not take PENTASA® 500mg slow-release tablets

- If you are allergic to mesalazine, salicylic acid or its derivatives (e.g. acetylsalicylic acid) or to any of the other ingredients of this medicine.
- If you have severe liver and renal function impairment.

Warnings and precautions

Talk to your doctor or pharmacist before taking PENTASA® 500mg slow-release tablets. Take special care with this medicine

- If you are allergic to sulphasalazine (risk of allergy to salicylates);
- If you currently have or have previously had liver and/or kidney disease;
- If you have a medical condition that can make you prone to bleeding;
- If you have an active peptic ulcer (stomach ulcer or duodenal ulcer);
- If you are on medication that may affect kidney function e.g. non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid;
- If you have lung diseases, in particular asthma;
- If you suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash. In such circumstances you should stop taking PENTASA® immediately.

While you are on treatment with this medicine, your doctor will normally arrange blood tests to check your kidney function especially at the beginning of treatment.

Other medicines and PENTASA® 500mg slow-release tablets

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use 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 leukaemia);
- Certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood).

In patients with a known hypersensitivity to sulphasalazine, treatment with PENTASA® 500mg slow-release tablets should only be commenced under careful medical supervision.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

PENTASA® 500mg slow-release tablets should not be used during pregnancy, except when the potential benefits of the treatment outweigh the possible hazards in the opinion of the doctor.

Breast-feeding

Blood disorders have been reported in newborns of mothers being treated with this medicine. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. Your doctor has to decide if breast-feeding is to be interrupted or if treatment with PENTASA® 500mg slow-release tablets should be given up. In doing so, the benefit of breast-feeding for the infant as well as the benefit of therapy for the woman has to be considered.

Driving and using machines

PENTASA® 500mg slow-release tablets have no effect on the ability to drive and use machines.

Note: The risk of colorectal cancer (CRC) is slightly increased in ulcerative colitis, observed effects of mesalazine in experimental models and patient biopsies support the role of mesalazine in prevention of colitis-associated CRC, with downregulation of both inflammation dependent and non-inflammation dependent signalling pathways involved in the development of colitis-associated CRC.

3. HOW TO TAKE PENTASA® 500mg SLOW-RELEASE TABLETS

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

The recommended dose is:

Adults:

For treatment of acute ulcerative colitis, your doctor will prescribe up to 4g mesalazine per day, divided in single doses. You may take up to 4 PENTASA® 500mg slow-release tablets twice a day.

For prophylaxis of further inflammatory episodes, your doctor will usually prescribe 1.5g mesalazine per day, e.g. 3 times a day 1 PENTASA® 500mg slow-release tablet.

For treatment of acute Crohn's disease, your doctor will prescribe up to 4g mesalazine per day, divided into 2 – 3 single doses, e.g. twice a day 2 – 4 or 3 times a day 2 – 3 PENTASA® 500mg slow-release tablets each (30 – 50 mg/kg body weight/day).

Children from the age of 6 years:

Ulcerative colitis (acute treatment and prophylaxis of acute ulcerative colitis) and Crohn's disease (acute treatment):

The dose given to children is up to the discretion of the physician and depends on the body weight. It is usually recommended that children with a body weight of up to 40 kg should receive half the dose given to adults and children with a body weight above 40 kg should receive the normal adult dose.

Method of administration:

Take the PENTASA® 500mg slow-release tablets without chewing, preferably between meals, with sufficient fluid or put them into water or fruit juice, stir and drink.

Duration of administration:

The duration of administration is up to the discretion of the treating physician. It depends on the course of the disease. PENTASA® 500mg slow-release tablets are suitable for long-term use.

Note:

The tablets consist of numerous microcapsules and thus seem to have grey specks. This pattern is normal. The covers of the microcapsules are excreted undigested. These covers may be visible in the faeces as white pin-size particles.

If you feel that the effect of PENTASA® 500mg slow-release tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more PENTASA® 500mg slow-release tablets than you should In the event of overdose, contact your doctor or nearest casualty department immediately.

If you forget to take PENTASA® 500mg slow-release tablets

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

There have been very few reports of a severe allergic reaction (including severe skin erosions that may affect the skin as the protective barrier of the body). The allergic reaction might lead to swelling of the face and neck and/or difficulty in breathing or swallowing (Quincke's oedema). If this happens contact your doctor or nearest casualty department immediately.

The most frequent side effects seen in clinical trials are diarrhoea, nausea, abdominal pain, headache, vomiting and rash.

Occasionally, hypersensitivity reactions and drug fever may occur.

Common (may affect up to 1 of 10 patients treated)

- Headache;
- Dizziness;
- Diarrhoea;
- Abdominal pain;
- Nausea;
- Vomiting;
- Rash;
- Flatulence.

Rare (may affect up to 1 of 1,000 patients treated)

- Inflammation of heart muscle or heart sac (myocarditis, pericarditis) which can cause shortness of breath and chest pain or palpitations (rapid or irregular heartbeats);
- Inflammation of the pancreas (pancreatitis) including symptoms like back and stomach pain;
- Increased amylase (enzyme that helps digest carbohydrates);
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare (may affect up to 1 of 10,000 patients treated)

- Anaemia and other blood disorders (decrease in the numbers of certain blood cells, which can cause unexplained bleeding, bruising, fever or sore throat)
- Hypersensitivity reactions such as allergic exanthema;
- Severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel;
- A condition affecting the nerves of the hands and feet, symptoms include tingling and numbness (peripheral neuropathy);
- Accumulation of fluid in the heart sac (pericardial effusion) which can cause chest pain or pressure;
- Allergic reactions and increase of connective tissue (fibrosis) in the lung, inflammation of the lining of the lungs or lung scarring (symptoms include coughing, bronchial cramps (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 or eyes) and/or pale bowel motions);
- Reversible hair loss;
- Muscle or joint pain;
- 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));
- Kidney disorders (symptoms include blood in the urine and/or swelling due to build up of fluid);
- Change in urine colour;
- Semen with a low concentration of sperm (oligospermia) (reversible);
- Allergic reactions and fever may occasionally occur.

There have been very few reports of benign intracranial hypertension in adolescents. Symptoms include headache, nausea, vomiting or visual and/or hearing disturbances.

Some of these side effects may be due to the bowel disease itself.

5. HOW TO STORE PENTASA® 500mg SLOW-RELEASE TABLETS

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 outer carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not freeze. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What PENTASA® 500mg slow-release tablets contain

Active ingredient: each slow-release tablet contains 500mg mesalazine.

The other ingredients are: povidone K30, ethylcellulose, magnesium stearate, talc, microcrystalline cellulose.

What PENTASA® 500mg slow-release tablets look like and contents of the pack

White-grey to pale brown, speckled, round tablets, scored and marked PENTASA on one side and 500mg on the other side. Pack with 100 or 300 slow-release tablets. Not all pack sizes are marketed.

Manufacturing Site

FERRING International Center SA,
Chemin de la Vergognausaz 50,
1162 St-Prex,
Switzerland.

Marketing Authorization Holder

FERRING GmbH,
Wittland 11,
D-24109 Kiel,
Germany.

This leaflet was last revised in January 2018.

To Report Side Effects Kingdom of Saudi Arabia

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Ext: 2317-2356-2340.
- SFDA Call Center: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

This is a Medicine

- A medicine is a product, which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period or treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep the medicine out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists