PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Pentasa 500 mg prolonged-release tablets
Pentasa 1 g prolonged-release tablets

Mesalazine

Read the entire package leaflet carefully before you start taking this medicine because it contains important information.
- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. See section 4.

What is in this package leaflet

1. What is Pentasa prolonged-release tablets and what is it used for?
2. What should you consider before taking Pentasa prolonged-release tablets?
3. How to take Pentasa prolonged-release tablets?
4. What side effects are possible?
5. How to store Pentasa prolonged-release tablets?
6. Contents of the pack and other information

1. WHAT IS PENTASA PROLONGED-RELEASE TABLETS AND WHAT IS IT USED FOR?

Pentasa contains mesalazine, an anti-inflammatory drug for the bowel, and is used for the following conditions:
- Colitis ulcerosa;
- Crohn's disease.

2. WHAT SHOULD YOU CONSIDER BEFORE TAKING PENTASA SLOW-RELEASE TABLETS?

Pentasa must not be taken,

- if you are allergic to salicylic acid derivatives or any of the other ingredients of this medicine listed in section 6.
- if you suffer from a stomach or intestinal disease.
- if you suffer from severe liver or kidney impairment.

Warnings and precautions

- If you have an abnormal tendency to bleed and have shown hypersensitivity reactions to salicylates in the past.
- It is desirable to examine the blood count before and regularly during treatment. The risk of a deviation in the blood count due to a medicine based on azathioprine, 6-mercaptopurine, or thioguanine may be increased if you take Pentasa at the same time.
- If you suffer from impaired liver and/or kidney function. If you use Pentasa long-term, regular monitoring of kidney function is desirable. The simultaneous use of other

medicines that are toxic to the kidneys, such as anti-inflammatory drugs (NSAIDs) and azathioprine, can increase the risk of kidney reactions.
If you have lung problems, especially asthma.
If you are taking other medicines. Please also read the section "Taking Pentasa with other medicines".
If hypersensitivity reactions to your heart have already occurred after using mesalazine (inflammation of the heart or the inner lining of the heart).
If you are being treated with certain medicines that inhibit blood clotting (medicines against thrombosis or for blood thinning).

Please talk to your doctor or pharmacist before taking Pentasa.

Taking Pentasa with other medicines

Inform your doctor or pharmacist if you are taking, have recently taken, or intend to take other medicines.

If you are already taking corticosteroids (anti-inflammatory drugs), you may start treatment with Pentasa. Pentasa can cause or exacerbate stomach discomfort through the use of corticosteroids. The simultaneous use of
Azathioprine, 6-mercaptopurine, or thioguanine with Pentasa can lead to suppression of bone marrow function. Regular monitoring of white blood cells is recommended.
Pentasa can enhance the effect of sulfonamides (drugs used in diabetes).
There is weak evidence that mesalazine may reduce the anticoagulant effect of warfarin.
The simultaneous use of mesalazine with other nephrotoxic drugs (drugs that can damage the kidneys) (for example, NSAIDs, azathioprine, or intravenous immunoglobulins) can increase the risk of nephrotoxic side effects (see also section "Warnings and Precautions").

Pregnancy, breastfeeding, and fertility

Pentasa must be used with caution during pregnancy, especially in the last 3 months due to the risk of bleeding. The underlying disease itself (inflammatory bowel disease) can increase the risks for the course of pregnancy. There are no relevant and well-controlled studies on the use of Pentasa in pregnant women. The limited published data on the use of mesalazine in humans do not show an increase in the overall percentage of congenital malformations. Some data indicate an increased number of preterm births, stillbirths, and cases of low birth weight. However, these adverse pregnancy outcomes are also associated with active inflammatory bowel disease.
A reduction in the number of white blood cells and platelets and anemia have been observed in newborns of mothers treated with Pentasa.

Pentasa must be used with caution during breastfeeding.
Pentasa passes into breast milk. There is only limited experience with the oral intake of Pentasa in breastfeeding mothers. Controlled studies with Pentasa administered during breastfeeding have not been conducted. Hypersensitivity reactions in the infant as well as diarrhea cannot be excluded. If diarrhea occurs in the infant, breastfeeding should be discontinued.

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Taking mesalazine is unlikely to affect driving and the ability to use machines.

3. HOW TO TAKE PENTASA SLOW-RELEASE TABLETS?

Always take this medicine exactly as agreed with your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

If there is no improvement, consult your doctor again.

The recommended dosage is

Adults and adolescents
Once daily or in divided doses. For example:

	Morning	midday	evening
DAILY DOSE = 1.5 g			
	1 tablet 500 mg	1 tablet 500 mg	1 tablet 500 mg
or	2 tablets 500 mg	-	1 tablet 500 mg or 1 tablet 1 g
	-	1 tablet 500 mg	
DAILY DOSE = 2 g			
	2 tablets 500 mg	-	2 tablets 500 mg
or	1 tablet 1 g		1 tablet 1 g
DAILY DOSE = 3 g			
	2 tablets 500 mg	2 tablets 500 mg	2 tablets 500 mg
or	1 tablet 1 g	1 tablet 1 g	1 tablet 1 g
DAILY DOSE = 4 g			
	4 tablets 500 mg	-	4 tablets 500 mg
or	2 tablets 1 g	-	2 tablets 1 g

Use in children

Children from 6 years
The dose for children is calculated by your doctor and depends on the child's body weight. Generally, it is recommended that half the adult dose be administered to children with a body weight up to 40 kg and the normal adult dose to children with a body weight over 40 kg.

Instructions for use and/or route of administration

Swallow the tablets with water or another drink. Do not dissolve the tablets.
The tablets may be divided to facilitate swallowing. Do not chew the tablets.

In case of stomach discomfort, the tablets can be taken during or immediately after a meal.

Your doctor will tell you how long you need to take Pentasa, or if you may reduce it. Do not stop the treatment early, as the disease may recur.

If you have taken more Pentasa than you should

If you have taken more Pentasa than you should, contact your doctor, pharmacist, or the poison control center (070/245.245) immediately.

There is no specific antidote. Treatment is supportive and tailored to the symptoms of the overdose. Hospital treatment involves careful monitoring of kidney function.

If you forget to take Pentasa

Take the missed dose as soon as possible and the next dose at the next recommended time. Do not take a double dose if you have forgotten the previous one.

If you stop taking Pentasa

Always consult your doctor if you plan to stop the treatment. If you stop the treatment, symptoms may return because the disease can recur.

If you have further questions about taking this medicine, ask your doctor or pharmacist.

4. WHAT SIDE EFFECTS ARE POSSIBLE?

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

Common (1/100, < 1/10)
Nervous system disorders: Headaches that must be reported to the doctor. Gastrointestinal disorders: Diarrhea, nausea, abdominal pain, vomiting, loss of appetite, and flatulence (these symptoms usually disappear on their own).
Skin and subcutaneous tissue disorders: Rash (including hives and skin redness) that must be reported to the doctor.

Rare (1/10,000, < 1/1,000)
Nervous system disorders: Dizziness.
Cardiac disorders: Inflammation of the heart and the inner lining of the heart.
Gastrointestinal disorders: Increased amylase (digestive enzyme) and inflammation of the pancreas.
Skin and subcutaneous tissue disorders: Increased sensitivity of your skin to sunlight and ultraviolet (UV) radiation (photosensitivity).

Very rare (< 1/10,000)
Blood and lymphatic system disorders: Blood count abnormalities such as Anemia (blood deficiency), aplastic anemia (blood deficiency due to bone marrow damage), agranulocytosis (very severe deficiency of white blood cells, accompanied by sudden high fever, severe sore throat, and mouth ulcers), neutropenia (reduction of a certain type of white blood cells), leukopenia (characterized by a deficiency of white blood cells and increased susceptibility to infections) (including granulocytopenia, a deviation characterized by a significant reduction of a certain type of white blood cells and increased susceptibility to infections), pancytopenia (reduction of all types of cells in the blood), thrombocytopenia (reduced number of platelets, characterized by bruising and tendency to bleed), and eosinophilia (increase of certain white blood cells) (as part of a hypersensitivity reaction).

Immune system disorders: Hypersensitivity reaction, including allergic Exanthema (form of skin rash), anaphylactic reaction (very severe, life-threatening hypersensitivity reaction with, among other things, the following symptoms: fever, itching all over the body, nausea, and severe drop in blood pressure), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (a (recurrent) condition characterized by red, raised spots that look like targets and are usually symmetrically distributed over the entire body) and Stevens-Johnson syndrome (SJS) (severe hypersensitivity reaction with (high) fever, red spots on the skin, joint pain, and/or eye inflammation); drug fever.
Nervous system disorders: Peripheral nerve disorder.
Respiratory, thoracic, and mediastinal disorders: Allergic alveolitis (acute inflammation from alveoli due to an allergic reaction to inhaled substances), allergic and fibrotic lung reactions (including shortness of breath, bronchospasm (tightness due to muscle spasm in the airways) and cough), pulmonary eosinophilia (increase in the number of white blood cells in the lung), interstitial lung disease (disease of the solid lung tissue), lung infiltration (consolidation of lung tissue) and pneumonitis (benign sudden inflammation of part of a lung lobe without general symptoms of illness).
Gastrointestinal disorders: Pancolitis (inflammation of the entire intestine).
Liver and biliary disorders: Abnormal liver tests and hepatotoxicity, including hepatitis (inflammation of the liver), cholestatic hepatitis (liver inflammation due to damage to the bile ducts), cirrhosis (liver disease due to alcohol) and liver failure.
Skin and subcutaneous tissue disorders: Hair loss (reversible).
Musculoskeletal, connective tissue and bone disorders: Bone pain, muscle pain and reactions that resemble lupus erythematosus (inflammatory-like reactions of the skin (with red, dry patches on the nose and cheeks) and/or internal organs).
Renal and urinary disorders: Renal dysfunction (including acute and chronic interstitial nephritis (inflammation of the kidneys, with symptoms such as blood in the urine, fever and pain on the side), nephrotic syndrome (kidney disorder) (kidney disease that can lead to swelling, especially in the face or around the eyes, the presence of protein in the urine, making it foamy and/or weight gain), renal failure (insufficient kidney function)) and discoloration of the urine.
Reproductive system and breast disorders: Semen with a low sperm concentration (oligospermia) (reversible).

It is important to know that various disorders of the aforementioned disorders can also be caused by the inflamed intestine.

Reporting of side effects
If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly via:
Federal Agency for Medicines and Health Products, Vigilance Department
Eurostation II, Victor Hortaplein 40/40, B-1060 Brussels
Website: www.fagg-afmps.be – E-Mail: patientinfo@fagg-afmps.be
By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE PENTASA PROLONGED-RELEASE TABLETS?

Keep this medicine out of the reach of children.

Pentasa 500 mg Prolonged-release tablets

Do not store above 25°C. Keep in the original package.

Pentasa 1 g Prolonged-release tablets
This medicine does not require any special storage conditions.

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

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. This will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pentasa contains

The active substance is mesalazine. Pentasa contains 500 mg or 1 g mesalazine/tablet.
The other ingredients are povidone, ethylcellulose, magnesium stearate, talc, and microcrystalline cellulose.

What Pentasa looks like and contents of the pack

Pentasa 500 mg prolonged-release tablets: Blister pack (Alu/Alu) or in wide-neck container with 90, 100, or 300 tablets.
Pentasa 1 g prolonged-release tablets: Blister pack (Alu/Alu) with 60 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder
Ferring N.V., Capucienenlaan 93C, B-9300 Aalst
Tel.: 053-72 92 00
E-Mail: ferringnvsa@ferring.be
Manufacturer
Ferring GmbH, Wittland 11, 24109 Kiel, Germany

Marketing authorization numbers

Pentasa 500 mg prolonged-release tablets (Blister pack): BE156055
Pentasa 500 mg prolonged-release tablets (wide-neck container): BE230991
Pentasa 1 g prolonged-release tablets: BE477306

Type of dispensing

Prescription only.

This package leaflet was last approved in 03/2018.