

Package leaflet: Information for the user

Salazopyrin® EN-tabs 500 mg Gastro-resistant tablets

sulfasalazine

Read all of this leaflet carefully before you take 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

What is in this leaflet:

1. What Salazopyrin EN-tabs are and what they are used for
2. What you need to know before you take Salazopyrin EN-tabs
3. How to take Salazopyrin EN-tabs
4. Possible side effects
5. How to store Salazopyrin EN-tabs
6. Contents of the pack and other information

1. What Salazopyrin EN-tabs are and what they are used for

The active substance in Salazopyrin EN-tabs is sulfasalazine which is an anti-inflammatory drug and belongs to a group of medicines called aminosalicylates. Your doctor may give you Salazopyrin EN-tabs to treat and manage inflammation caused by rheumatoid arthritis or inflammatory bowel disease.

The main forms of inflammatory bowel disease are Ulcerative Colitis and Crohn's disease. Although the diseases have some features in common, there are some important differences:

Ulcerative Colitis is an inflammatory disease which affects only the large bowel (colon and back passage). The lining of the bowel becomes inflamed (red and swollen) and symptoms include abdominal pain and diarrhoea (which may contain blood and mucus). Salazopyrin EN-tabs are used to control the flare-ups of ulcerative colitis. They may also be used at lower doses to prevent more flare-ups of ulcerative colitis.

Crohn's disease is an inflammatory disease which may affect any part of the digestive system from the mouth to the anus, but it most commonly affects the last part of the small bowel and the first part of the large bowel. Symptoms include abdominal pain and diarrhoea (which may be bloody). Salazopyrin EN-tabs are used to control the flare-ups of Crohn's Disease.

Rheumatoid arthritis

Salazopyrin EN-tabs can be given when a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs, e.g. aspirin and ibuprofen) are not working. Salazopyrin can help prevent damage to joints, and reduce swelling and stiffness, caused by rheumatoid arthritis.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Salazopyrin EN-tabs

Do not use Salazopyrin EN-tabs:

- if you are allergic (hypersensitive) to any of the ingredients of Salazopyrin EN-tabs (listed in section 6).
- if you are allergic (hypersensitive) to salicylates (e.g. aspirin) or sulfonamides (e.g. a certain type of antibiotic).
- if you have a disease known as porphyria (a rare blood pigment disorder). Your doctor will have already told you if you have this disease.
- if you have jaundice (yellowing of the skin or eyes).

Salazopyrin EN-tabs are **not to be used in children under 2 years** of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Salazopyrin EN-tabs:

- If you suffer from problems with your liver or kidneys-
- If you suffer from blood disorders, such as a low number of red or white blood cells.
- If you suffer from glucose-6-phosphate dehydrogenase deficiency (an inherited condition in which the body doesn't have enough of an enzyme known as glucose-6 dehydrogenase which helps red blood cells to function normally).
- If you have ever had asthma.
- If you have a history of recurring chronic infections or an underlying condition which may predispose you to infections

Tell your doctor if you are taking or have recently taken Salazopyrin EN-tabs, or any other sulfasalazine containing products, because they may affect results of blood and urine tests.

Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency potentially resulting in serious blood disorders (e.g., macrocytosis and pancytopenia), this can be normalised by administration of folic acid or folinic acid (leucovorin).

Because sulfasalazine causes crystalluria and kidney stone formation, adequate fluid intake should be ensured during treatment.

Potentially life-threatening skin rashes (exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Salazopyrin EN-tabs, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Salazopyrin EN-tabs you must not be re-started on Salazopyrin EN-tabs at any time. If you develop a rash or these skin symptoms, stop taking Salazopyrin

EN-tabs, seek immediate advice from a doctor and tell him that you are taking this medicine.

If you experience rash or fever or swollen gland while taking Salazopyrin you should speak to your doctor as this may be a sign of DRESS (drug rash with eosinophilia and systemic symptoms). Your doctor may advise you to stop taking Salazopyrin.

Children and adolescents

Sulfasalazine is not recommended if you are a child and have systemic-onset juvenile rheumatoid arthritis (Stills disease).

Other medicines and Salazopyrin EN-tabs

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines without a prescription.

In particular, the following medicines as they may interact with Salazopyrin EN-tabs:

- digoxin, used to treat heart failure
- folic acid or folate, sometimes taken during the first few weeks of pregnancy to reduce the risk of neural tube defects, e.g. Spina Bifida
- azathioprine and mercaptopurine, drugs used to help to suppress your body's immune response in organ transplantation and certain chronic inflammations (e.g. rheumatoid arthritis)
- methotrexate, used to treat rheumatoid arthritis.

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 for advice before taking this medicine. There have been reports of diarrhoea or blood in the stools of babies of breast-feeding mothers taking Salazopyrin EN-tabs. If this happens you must stop taking salazopyrin and see your doctor as soon as possible.

There have been reports of babies with neural tube defects born to mothers who were exposed to sulfasalazine during pregnancy, although the role of sulfasalazine in these defects has not been established. Sperm deficiency, a cause of infertility may occur in men treated with sulfasalazine. Discontinuation of the medicine appears to reverse these effects within 2 to 3 months.

Driving and using machines

Salazopyrin EN-tabs are unlikely to affect your ability to drive or use machinery.

3. How to take Salazopyrin EN-tabs

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

The tablets should be taken with a glass of water and should be swallowed whole. Do not crush or chew the tablets.

The recommended doses for the following conditions are:

Ulcerative Colitis and Crohn's Disease

Adults and the Elderly

• Severe Flare-Ups

2-4 tablets four times a day, with other medicines such as steroids.

Do not leave more than 8 hours between the evening and following morning dose.

• Mild/Moderate Flare-Up

2-4 tablets four times a day, but not always with other medicines.

• Maintenance dose to control your flare ups

Once the flare-up is controlled the dose is slowly reduced to 4 tablets each day. Your doctor will tell you how to reduce your dose. This lower dose will be continued indefinitely to help stop other flare-ups.

Children 2 years of age and over

Your doctor will tell you what dose your child will need to use. This will be based on your child's weight.

- The tablets should start to work in a few days. Your doctor will advise you on how long you should take these tablets for.
- If they work well, you may be using them for some time because inflammatory bowel disease may be a lifelong condition.

For Rheumatoid arthritis

Adults and the elderly - Start on one tablet each day for the first week. Then, increase the dose by one tablet a day each week to a maximum of 6 tablets daily as shown below:

	1 st week	2 nd week	3 rd week	4 th week
Morning	-	1	1	2
Evening	1	1	2	2*

*etc to a maximum of 6 tablets per day.

Do not take more than 6 tablets a day.

Children - No recommendations.

How long should you use these tablets?

Salazopyrin EN-tabs may take some months to have a full effect, so you should keep taking them.

- You may notice some effect after a few weeks.
- When they start to work you will feel less stiffness in your joints, especially in the mornings.
- If they work well, you may be using them for some time.

Ensure that you drink adequate fluids whilst you are taking this medicine. This is to avoid problems with your kidneys.

If you take more Salazopyrin EN-tabs than you should

The most common symptoms of overdose are nausea and vomiting. If you experience any of these contact your nearest hospital casualty department, or tell your doctor immediately, if you have taken too many tablets (an overdose) or if a child has taken your medicine.

Please take this leaflet and these tablets with you to the hospital casualty department or to your doctor.

If you forget to take Salazopyrin EN-tabs

If you forget to take a dose, just take the next dose as usual. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Salazopyrin EN-tabs

Do not stop taking this medicine or alter the dose you are currently taking without seeing your doctor first.

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.

Stop taking Salazopyrin EN-tabs and tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious:

- An allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- Jaundice (yellowing of the eyes or skin).
- If you develop a severe skin rash that causes blistering, (this can affect the mouth and tongue). Potentially life-threatening skin rashes (exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported very rarely (see section 2). Your doctor will stop your treatment in these cases.
- If you have a serious skin condition with a rash (sometimes confined to the cheeks and bridge of the nose) peeling skin or blistering. It may be triggered or aggravated by sunlight. Should this occur, **stop taking this medicine, avoid strong sunlight and contact your doctor promptly.**
- If you are generally feeling unwell, have a fever, have pains in your joints, hives, swollen glands, rash and itching. These may be signs of a condition known as serum sickness. Your doctor will stop your treatment in these cases.
- If you are breast feeding stop taking this medicine, if you notice blood in your child's stool or diarrhoea.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as they will stop treatment in these cases:

- If you notice any unexplained bleeding.
- If you notice bruising, fever, rash, pallor (paleness), a severe sore throat or tiredness. These may be the first signs of an abnormality of the blood, including decreases in the number of red cells, white cells or platelets. Your doctor may take regular blood samples to test for these effects.

Tests on your blood, kidneys, liver and urine

Your doctor will take blood tests to check your blood count as well as your kidney and liver function before you start your treatment and regularly during treatment. Your doctor may also test your urine for protein and blood.

Other side effects that may occur are:

Very common: may affect more than 1 in 10 people

- Indigestion, heartburn
- feeling sick (nausea)

Common: may affect up to 1 in 10 people

- dizziness
- headache
- changes in taste
- ringing in the ears
- cough
- itching of the skin
- purple discolouration's on the skin
- joint pain
- protein in urine
- fever

Uncommon: may affect up to 1 in 100 people

- depression
- shortness of breath
- abdominal pains
- diarrhoea
- being sick
- hair loss
- hives
- puffiness around the eyes and face
- yellowing of the skin or whites of the eyes (jaundice)

Not known: frequency cannot be estimated from the available data

- allergic reactions (rash, itching, shock)
- inflammation of the lining of the brain
- severe diarrhoea
- other blood disorders including anaemia, enlarged glands (lymph nodes), glandular fever, persistent sore throat
- blood vessel inflammation
- loss of appetite
- hallucinations
- difficulty sleeping
- fits, jerky, uncontrolled movements
- changes in mental state, loss of memory
- changes in smell
- blood shot eyes and eye infections
- inflammation of the sac surrounding the heart (pericarditis)
- inflammation of the heart muscle (myocarditis)
- bluish tint or paleness to skin due to poor circulation
- lung complications with breathlessness
- inflammation of the salivary glands on either side of the face
- inflamed mouth (stomatitis)
- kidney inflammation and kidney pain, kidney stones
- liver disease (hepatitis)
- inflammation of the pancreas – pancreatitis
- rash, reddening or blistering of the skin, eczema, swelling of the skin
- tingling, numbness, pain in hands and feet
- blood and crystals in urine
- urine or motions may become a yellow/orange colour which is normal and harmless. (See section 6)
- temporary infertility in men. Fertility returns when treatment is stopped. Normal contraception should still be used.

- dryness of the mouth and eyes
- deficiency in folic acid (may cause fatigue).

Very rarely sulfasalazine has caused permanent staining of extended wear soft contact lenses. (See section 6).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Salazopyrin EN-tabs

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 carton, bottle or blister after EXP. The expiry date refers to the last day of that month.

Do not store your tablets above 25 °C. Keep the bottle tightly closed in order to protect from moisture.

Blister: Store in the original package.

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 protect the environment.

6. Contents of the pack and other information

What Salazopyrin EN-tabs contain

The active substance is sulfasalazine. Each tablet contains 500 mg of sulfasalazine. Other ingredients are maize starch, magnesium stearate, colloidal anhydrous silica, cellulose, propylene glycol, carnauba wax, macrogol, glyceryl monostearate and talc.

The tablets imported from Italy also contain povidone and beeswax.

The tablets imported from Hungary also contain white wax.

The tablets imported from The Czech Republic also contain povidone and white wax.

What Salazopyrin EN-tabs looks like and contents of the pack

The tablets are orange/yellow in colour and are oval-shaped. They have "KPh" imprinted on one side and "102", on the other. The tablets are the colour of the medicine itself. The tablets contain no artificial colouring.

Salazopyrin Tablets are available in blister packs or bottles of 100 tablets contained in an outer cardboard carton. Not all pack sizes may be marketed.

Product procured from within the EU, repackaged and distributed by the parallel product authorization holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland

Parallel Product Authorisation Number: PPA 465/160/1

Manufacturer

Pharmacia & Upjohn S.p.A, Sweden or Kemwell AB, Björkgatan 30, 75182 Uppsala, Sweden or Recipharm Uppsala AB, Björkgatan 30, SE-751 82 Uppsala, Sweden.

Salazopyrin is a registered trademark of Pfizer Health AB.

General Advice

Because the tablets are coloured yellow they may cause your urine or motions to become a yellow/orange colour. This is normal and harmless but can stain fabric. Any Salazopyrin soiled fabric should be put in to soak.

Difficult stains may be removed with a solution of washing soda. Always test the effect of soda on a small piece of the fabric first. Then apply a mild acid such as white vinegar.

Sulfasalazine has caused permanent staining of extended wear soft contact lenses, although this happens very rarely. Daily-wear soft contact lenses and gas permeable lenses respond to standard cleaning if this happens.

Where can I get more advice about Ulcerative Colitis and Crohn's Disease?

The National Association for Colitis and Crohn's Disease (NACC) has local groups which offer meetings, events and information for patients. They may be contacted at NACC, P.O. Box 205, St. Albans, Herts, AL1 1AB, UK.

This leaflet was last revised in December 2019.