

Package leaflet: Information for the user
Salazopyrin® 500 mg Suppositories
sulfasalazine

Read all of this leaflet carefully before you are given 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.

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1. What Salazopyrin Suppositories are and what they are used for

The active substance in Salazopyrin Suppositories is sulfasalazine which is an anti-inflammatory medicine and belongs to a group of medicines called aminosalicylates.

Your doctor may give you Salazopyrin Suppositories to treat and manage 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 Suppositories act locally in the end part of the bowel (the back passage) to reduce the inflammation and are used to control the 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 Suppositories act locally in the end part of the bowel (the back passage) and are used to control the flare-ups of Crohn's Disease.

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 use Salazopyrin Suppositories

Your doctor will perform complete blood counts and liver function tests before starting Salazopyrin and every second week during the first three months of therapy. During the second three months, the same tests should be done once monthly and thereafter once every three months, and as clinically indicated. Urine analysis and an assessment of kidney function should also be done in all patients initiating treatment with Salazopyrin. For patients with baseline renal impairment, treatment with Salazopyrin should only be initiated if the benefits are considered to outweigh risk. Thereafter, periodic renal function monitoring, especially in the early months of treatment, should be conducted by your doctor during treatment with Salazopyrin. Treatment should be discontinued if renal function deteriorates.

Do not use Salazopyrin Suppositories:

- if you are allergic to sulfasalazine or any of the other ingredients of this medicine.
- if you are allergic 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.

Salazopyrin Suppositories are **not to be used in children under 2 years** of age.

Warnings and precautions

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

Talk to your doctor or pharmacist before taking Salazopyrin Suppositories:

- if you have ever had any problems with your liver or kidneys.
- if you have been told by your doctor that you have an inherited condition in which the body doesn't have enough of an enzyme known as glucose-6-dehydrogenase which helps red blood cells function normally.
- if you have ever had asthma.
- if you are a child and have arthritis.
- if you have a history of recurring chronic infections or an underlying condition which may predispose you to infections.

Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency potentially resulting in serious blood disorders (e.g., red blood cells that are larger than normal and lower-than-normal number of red and white blood cells and platelets in the blood), 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 Suppositories, 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 exfoliative dermatitis, Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Salazopyrin Suppositories you must not be re-started on Salazopyrin Suppositories at any time. If you develop a rash or these skin symptoms, stop taking Salazopyrin Suppositories, seek immediate advice from a doctor and tell your doctor that you are taking this medicine.

Severe, life-threatening allergic reactions such as Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) have been reported in patients taking various drugs including Salazopyrin Suppositories. It is important to note that early signs of severe allergy, such as fever or swollen lymph nodes, may be present even though rash is not evident. If such signs or symptoms are present, you should seek immediate advice from a doctor. Salazopyrin Suppositories should be discontinued if an alternative cause for the signs or symptoms cannot be established.

Children and adolescents

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

Tests on your blood, kidneys, liver and urine

Your doctor will be taking blood tests to check your blood, your kidneys before you start treatment and regularly during treatment. They will also measure substances produced by your liver known as enzymes (liver function tests) before you start treatment and at regular intervals. They may also test your urine for protein and blood.

Other medicines and Salazopyrin Suppositories

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, the following medicines may interact with Salazopyrin Suppositories:

- any medicine for high blood sugar/diabetes.
- methenamine, an antibiotic for treating urinary tract infections.
- digoxin, used to treat heart failure.
- folate, sometimes taken during the first few weeks of pregnancy to reduce the risk of birth defects of the brain, spine or spinal cord, e.g., Spina Bifida.
- azathioprine and mercaptopurine – medicines used to help to suppress your body's immune response in organ transplantation and certain chronic inflammations such as rheumatoid arthritis.
- methotrexate, used to treat rheumatoid arthritis.

Pregnancy, breast-feeding and fertility

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

You should avoid breast-feeding while taking this medicine. There have been reports of diarrhoea or blood in the stools of babies of breast-feeding mothers taking Salazopyrin Suppositories. If this happens you must stop taking Salazopyrin Suppositories and see your doctor as soon as possible.

There have been reports of babies with birth defects of the brain, spine or spinal cord born to mothers who were exposed to sulfasalazine during pregnancy, although the role of sulfasalazine in these defects has not been established.

Low sperm count and 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 Suppositories is unlikely to affect your ability to drive or use machinery.

3. How to use Salazopyrin Suppositories

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

Do not swallow Salazopyrin Suppositories.

Salazopyrin Suppositories must be inserted into the back passage.

Firstly, empty your bowel if possible, then using your finger, push the suppositories well into the back passage. You may have the urge to pass the suppositories out again, but this should ease after a few minutes when they have melted. The suppositories melt at body temperature so handle them as little as possible.

The recommended doses for the following conditions are:

Ulcerative Colitis and Crohn's' Disease

• Adults and the Elderly

As described above insert two suppositories in the morning and two at bedtime, after emptying your bowel. After about three weeks your doctor may tell you to reduce the dose.

• 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.

You may be given a medicine by mouth as well as these suppositories to control your condition

How long should you use these suppositories?

How long you use these suppositories depends on how well the suppositories suit you.

- The suppositories should start to work in a few days.
- If they work well, you may be using them for some time because inflammatory bowel disease may be a lifelong condition.

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

If you use more Salazopyrin Suppositories 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 suppositories (an overdose) or if a child has taken your medicine.

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

If you miss a dose of Salazopyrin Suppositories

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

If you stop taking Salazopyrin Suppositories

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects with Salazopyrin Suppositories are fewer than the equivalent treatment by mouth.

Stop taking Salazopyrin Suppositories 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).
- 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, or toxic epidermal necrolysis (TEN)) have been reported very rarely (see section 2 for a list of some of the possible symptoms). 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**, once you notice blood in stools or diarrhoea in newborn.

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.

Discontinue treatment with Salazopyrin while awaiting the results of blood tests.

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
- Difficulty sleeping
- Headache
- Changes in taste
- Abdominal pains
- Diarrhoea
- Being sick
- Ringing in the ears
- Blood shot eyes
- Inflamed mouth (stomatitis)
- Cough
- Itching of the skin
- Purple discolourations on the skin
- Joint pain
- Protein in urine
- Fever

Uncommon (may affect up to 1 in 100 people)

- Depression
- Fits, jerky, uncontrolled movements
- Loss of balance
- Shortness of breath
- 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)

- 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
- Changes in mental state
- Changes in smell
- 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
- Kidney inflammation and kidney pain, kidney stones
- Liver disease (hepatitis)
- Yellowing of the skin or whites of the eyes (jaundice)
- Inflammation of pancreas, which causes severe pain in the abdomen and face
- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salazopyrin Suppositories

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 pack after EXP. The expiry date refers to the last day of that month.

Do not store the medicine above 25°C.

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 Suppositories contain

The active substance is sulfasalazine. Each suppository contains 500 mg of sulfasalazine. Other ingredients are hard fat, PVP (povidone).

What Salazopyrin Suppositories looks like and contents of the pack

The suppositories are yellow/orange in colour, have no smell and are torpedo shaped. The suppositories are the colour of the medicine itself. They contain no artificial colouring.

This medicine is available in packs containing either 10 or 50 suppositories.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation for Salazopyrin Suppositories is held by:
Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

The manufacturer of this medicine is:
Recipharm Uppsala AB, Björkgatan 30, Uppsala Domkyrkofors, Uppsala, 753 23
Sweden.

For any information about this medicine, please contact: Medical Information, Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

General Advice

Because the suppositories are coloured yellow/orange 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.

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