

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.

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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, proctocolitis, proctitis 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

Do not use Salazopyrin Suppositories :

- if you are allergic (hypersensitive) to any of the ingredients of Salazopyrin Suppositories (listed in section 6).
- 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 Suppositories are **not to be used in children under 2 years** of age.

Warnings and precautions

Medicines are not always suitable for everyone. Talk to your doctor or pharmacist before taking Salazopyrin suppositories:

- If you suffer from problems with your liver or kidneys
- If you suffer from blood disorders such as low numbers of red or white blood cells.
- If you suffer from G6PD deficiency (an inherited condition in which the body doesn't have enough of an enzyme known as glucose-6-phosphate 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., 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 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 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 him that you are taking this medicine.

DRESS Syndrome a severe, life-threatening, allergic reaction has been reported in patients taking various medicines including Salazopyrin. This condition is often severe, and it can result in death if not diagnosed early. A patient who is experiencing DRESS syndrome may first notice a fever or swollen lymph nodes even though rash is not evident. If such signs or symptoms are present, you should seek immediate advice from a doctor. Salazopyrin 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).

Other medicines and Salazopyrin Suppositories

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 Suppositories:

- 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

If you require any medical tests it is important that you tell the doctor you are taking Salazopyrin as this medicine can affect the results of some tests.

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 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.

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

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 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.

Unless your doctor has told you otherwise, the recommended doses for the following conditions are:

Ulcerative Colitis and Crohns' 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.

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

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

How long should you use these suppositories for?

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 life long condition.

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 used too many suppositories 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 forget a dose of Salazopyrin Suppositories

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 Suppositories

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. Side effects with Salazopyrin Suppositories are fewer than with Salazopyrin tablets.

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).
- 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 will 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 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 of the skin
- joint pain
- protein in urine
- fever

Uncommon: may affect 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
- deficiency in folic acid (may cause fatigue)
- Dryness of the mouth and eyes

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST

Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

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.

Store below 25°C.

Do not throw away 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 500mg of sulfasalazine.

Other ingredients are Hard Fat and 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

Pharmacia Laboratories Ltd., Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

Manufacturer Kemwell AB, 75182 Uppsala, Sweden.

Company contact address

For further information about this medicine, please contact Medical Information at the following address:

Pharmacia Ireland Limited, 9 Riverwalk, National Digital Park, Citywest Business Campus,
Dublin 24, Ireland.
Telephone 1800 633 363

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.

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, United Kingdom.

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