Salazopyrin® Tablets

500 mg

Sulfasalazine

POM

112 Tablets

Each tablet contains sulfasalazine 500 mg.

Use as directed by a doctor.

Oral use.

Store below 25°C.

Read the leaflet before use.

Keep out of the reach and sight of children.

MA Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK
PL: 00057/1044

Peel back for package leaflet
Patient Information Leaflet
Salazopyrin® Tablets 500 mg
sulfasalazine

In this leaflet:
1. What Salazopyrin Tablets are and what they are used for
2. Before you take Salazopyrin Tablets
3. How to take Salazopyrin Tablets
4. Possible side effects
5. How to store Salazopyrin Tablets
6. Further information

Read all of this leaflet carefully before you take this medicine
• 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 any of the side effects gets serious, or if you notice any side effects not listed in this
  leaflet, please tell your doctor or pharmacist.

1. What Salazopyrin Tablets are and what they are used for
The active substance in Salazopyrin Tablets is sulfasalazine which is an anti-
inflammatory drug and belongs to a group of medicines called aminosalicylates.
Your doctor may give you Salazopyrin Tablets 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 Tablets 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 Tablets are used to control the flare-ups of Crohn’s Disease.

2. Before you take Salazopyrin Tablets
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 periodically during treatment with Salazopyrin. Thereafter, monitoring will be performed as your doctor requires.

Do not use Salazopyrin Tablets if you
• are allergic (hypersensitive) any of the ingredients of Salazopyrin Tablets.
• are allergic (hypersensitive) to salicylates (e.g. aspirin) or sulfonamides (e.g. a certain type of antibiotic).
• have a disease known as porphyria (a rare blood pigment disorder). Your doctor will have already told you if you have this disease.
Salazopyrin Tablets are not to be used in children under 2 years of age.

Take special care with Salazopyrin Tablets
If the answer is YES to any of these questions tell your doctor or pharmacist before taking this medicine:
• Have you ever had any problems with your liver or kidneys?
• Have you 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?
• Have you ever had asthma?
• If you are a child and have arthritis?

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.

Taking other medicines
Tell your doctor or pharmacist if you are taking the following medicines as they may interact with Salazopyrin tablets:
• 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 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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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. 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 tablets. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
Salazopyrin tablets are unlikely to affect your ability to drive or use machinery.

**3. How to take Salazopyrin Tablets**
The tablets should be taken with a glass of water and should be swallowed whole. Do not crush or chew the tablets. Unless your doctor has told you otherwise, the usual doses for the following conditions are:

**Ulcerative Colitis**
*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 may be continued for some time 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.

**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.

**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.

**How long should you use these tablets?**
How long you use these tablets depends on how well the tablets suit you.
For Ulcerative Colitis and Crohn’s Disease
• The tablets 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.
• Don’t stop using the tablets just because you feel better without talking to your doctor.

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 Tablets than you should, 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 miss a dose of Salazopyrin Tablets
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 missed one.

4. Possible side effects
Like all medicines, Salazopyrin Tablets can cause side effects, although not everybody gets them.

Stop taking Salazopyrin Tablets 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). These may be signs of a condition known as Stevens Johnson Syndrome, or toxic epidermal necrolysis (TEN). 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 side-effects which may affect more than 1 person in 10 are listed below:**
- Indigestion, heartburn
- Feeling sick (nausea)

**Common side-effects which may affect more than 1 person in 100 are listed below:**
- 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
- Joint pain
- Protein in urine
- Fever

**Uncommon side-effects which may affect more than 1 person in 1000 are listed below:**
- Depression
- Fits, jerky, uncontrolled movements
- Loss of balance
- Shortness of breath
- Hair loss
- Hives
- Puffiness around the eyes and face

**Since introduction to the market the following side-effects have been reported:**
- Inflammation of the lining of the brain
- Severe diarrhoea
- Other blood disorders including anaemia, enlarged glands (lymph nodes)
- 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 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,
- 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,
- Tingling, numbness, pain in hands and feet
- Blood in urine
- Urine or motions may become a yellow/orange colour which is normal and harmless. (See section 6 General Advice for further information)
- Temporary infertility in men. Fertility returns when treatment is stopped. Normal contraception should still be used.

Very rarely sulfasalazine has caused permanent staining of extended wear soft contact lenses. (See section 6 General Advice for further information).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Salazopyrin Tablets
Keep out of the reach and sight of children.
Do not use Salazopyrin Tablets after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.
Store your tablets below 25°C in a dry place.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information
What Salazopyrin Tablets contain
The active substance is sulfasalazine. Each tablet contains 500mg of sulfasalazine. Other ingredients are maize starch, PVP (povidone), magnesium stearate, colloidal silicon dioxide.

What Salazopyrin Tablets look like and contents of the pack
The tablets are yellow in colour, and are round. They have “KPh” imprinted on one side and “101”, on the other. The tablets are the colour of the medicine itself. They contain no artificial colouring.
Salazopyrin is supplied in bottles. Each bottle contains 112 tablets.

**Marketing Authorisation Holder and Manufacturer**
The marketing authorisation for Salazopyrin Tablets is held by:
Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.
Salazopyrin Tablets are made by:
Recipharm Uppsala AB, 75182 Uppsala, Sweden.
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

**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.

This leaflet was last revised in 12/2016.

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