

PACKAGE LEAFLET: INFORMATION FOR THE USER

SALAZOPYRIN EN

500mg Enteric-coated tablets

SULFASAZINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What SALAZOPYRIN EN is and what it is used for
2. Before you take SALAZOPYRIN EN
3. How to take SALAZOPYRIN EN
4. Possible side effects
5. How to store SALAZOPYRIN EN
6. Further information

1. WHAT SALAZOPYRIN EN IS AND WHAT IS IT USED FOR

The active substance in SALAZOPYRIN EN is sulfasalazine which is an anti-inflammatory drug and belongs to a group of medicines called aminosalicylates.

Your doctor may give you SALAZOPYRIN EN to treat and manage inflammatory bowel disease or to treat rheumatoid arthritis.

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 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 are used to control the flare-ups of Crohn's Disease.

Rheumatoid arthritis

SALAZOPYRIN EN are usually given when a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs e.g. aspirin and ibuprofen) are not working. They help prevent damage to your joints and work slowly to reduce swelling and stiffness in your joints.

2. BEFORE YOU TAKE SALAZOPYRIN EN

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 take SALAZOPYRIN EN if you

- are allergic (hypersensitive) to any of the ingredients of SALAZOPYRIN EN.
- 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 EN are **not to be used in children under 2 years** of age.

Take special care with SALAZOPYRIN EN

If you answer **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 and 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 EN:

- 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 bodies immune response in organ transplantation and certain chronic inflammations such as 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 EN.

Driving and using machines

SALAZOPYRIN EN is unlikely to affect your ability to drive or use machinery.

3. HOW TO TAKE SALAZOPYRIN EN

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

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

For Inflammatory bowel disease:

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.

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 in table.

	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?

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

For Inflammatory bowel disease (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 life long condition.
- Don't stop using the tablets just because you feel better without talking to your doctor.

For Rheumatoid arthritis

- SALAZOPYRIN EN 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.
- 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 medicines. This is to avoid problems with your kidneys.

If you take more SALAZOPYRIN EN 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 EN

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, SALAZOPYRIN EN can cause side effects, although not everybody gets them.

Stop taking SALAZOPYRIN EN 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 will 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)
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- 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)
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- 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)
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- 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 EN

Keep out of the reach and sight of children.

Do not use SALAZOPYRIN EN after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Store 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 EN contain

The active substance is sulfasalazine. Each tablet contains 500mg of sulfasalazine. Other ingredients are maize starch, povidone, magnesium stearate, colloidal silicon dioxide.

The tablet enteric coating contains cellulose acetate phthalate, PVP (propylene glycol), bees wax, carnauba wax, self emulsifying glyceryl monostearate and talc.

What SALAZOPYRIN EN looks like and contents of the pack

The tablets are yellow in colour, and are oval-shaped. They have “Kph” imprinted on one side and “102”, on the other. They are coated with a film, which stops them breaking up until they leave the stomach. 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

Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.

Manufacturer

SALAZOPYRIN EN are made by: Kemwell AB, 75182 Uppsala, Sweden.

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 happened very rarely. Daily-wear soft contact lenses and gas permeable lenses respond to standard cleaning if this happens.