

SALAZINE ENTERIC COATED TABLET

Sulfasalazine (500 mg)

What is in this leaflet

1. What SALAZINE is used for
2. How SALAZINE works
3. Before you use SALAZINE
4. How to use SALAZINE
5. While you are using it
6. Side effects
7. Storage and Disposal of SALAZINE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What SALAZINE is used for

SALAZINE is used to treat and manage ulcerative colitis and Crohn's disease which are inflammatory bowel diseases.

SALAZINE is also used to treat rheumatoid arthritis, which is a painful joint disease.

How SALAZINE works

SALAZINE contains the active ingredient sulfasalazine. It is an anti-inflammatory drug and belongs to a group of medicines called aminosalicylates. Ulcerative colitis and Crohn's disease cause inflammation of the intestine, leading to such problems as abdominal pain and diarrhoea. SALAZINE can be used to control these symptoms and help prevent the disease from flaring up. It also can help prevent damage to joints and reduce swelling and stiffness in joints.

Before you use SALAZINE

- *When you must not use it*

Do not take SALAZINE if you:

- are allergic (hypersensitive) to sulfasalazine or any ingredients in the formulation.
- are allergic (hypersensitive) to salicylates (e.g. aspirin) or sulfonamide (e.g. certain type of antibiotic).
- have any form of intestinal or urinary obstruction.
- have a rare blood pigments disorder known as porphyria.

Do not give SALAZINE to children under 2 years of age.

If you are not sure whether you should start taking this medicine, consult your doctor.

- *Before you start to use it*

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- are pregnant, think you may become pregnant or are trying to become pregnant.
- are breastfeeding or planning to breastfeed.
- have severe allergy or bronchial asthma (wheezing or shortness of breath).
- have kidney or liver problems or any form of blood disorder.
- have severe hypersensitivity reactions that may include internal organ involvement.
- have severe, life-threatening, systemic hypersensitivity reactions such as drug rash with eosinophilia and systemic symptoms (DRESS).
- have serious skin reactions.
- have glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- have a history of recurring or chronic infections. If you develop a new infection while taking SALAZINE, talk to your doctor.

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

SALAZINE is not recommended for children with systemic onset juvenile rheumatoid arthritis.

Low sperm count, 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.

Your doctor will perform complete blood counts and liver function tests before starting SALAZINE 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. Assessment of kidney function (including urine test) should also be done periodically during treatment with SALAZINE. Thereafter, monitoring will be performed as your doctor requires.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription.

Some medicines can interfere with your treatment. Tell your doctor if you are taking any of the following:

- Digoxin (used to treat heart failure).
- Folic acid (used during pregnancy).
- Azathioprine and thiopurine 6-mercaptopurine (help to suppress your body's immune response in organ transplantation and certain chronic inflammation such as rheumatoid arthritis).
- Methotrexate (used to treat rheumatoid arthritis and some cancers).
- Medicines to lower blood sugar or control diabetes.

Pregnancy and lactation

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss the possible risks and benefits of taking SALAZINE during pregnancy and breastfeeding. 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.

SALAZINE is found in low level in breast milk. Caution should be given, particularly if breastfeeding premature infants or those with glucose-6-phosphate dehydrogenase (G6PD) deficiency. There have been reports of diarrhoea or blood in the stools of babies of breastfeeding mothers taking this medicine. If this happens you must stop taking SALAZINE and see your doctor as soon as possible.

How to use SALAZINE

Always take SALAZINE according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

- *How much to use*

Inflammatory Bowel Disease:

Adults:

- Severe flare-up: 2 to 4 tablets, 3 to 4 times

a day, usually with other medicines such as steroids.

- Mild/Moderate flare-up: 2 tablets, 3 to 4 times a day.
- Maintenance dose: Once the flare-up is controlled, your doctor may gradually lower your dose, as your condition improves, to 4 tablets a day. This lower dose should be continued to prevent further flare-ups.

Children 2 years of age and over:

Your doctor will determine the proper dose, taking into account the age and weight of the child.

Rheumatoid Arthritis:

Adults:

The usual starting dose is 1 tablet each day for the first week. Then, increase the dose by 1 tablet a day each week to a maximum of 6 tablets a day in divided doses.

Children:

SALAZINE is not recommended for treating rheumatoid arthritis in children.

- When to use it

Use as directed by your doctor or pharmacist. SALAZINE is best taken after meals or with food to lessen stomach upset. Swallow the tablets whole with a full glass of water. Do not crush, chew or break the tablet.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

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

- How long to use it

Continue to take your medicine for as long as your doctor recommends.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may

have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the carton or any remaining tablets you have with you.

Symptoms of overdose may include nausea, vomiting, abdominal pain, drowsiness or convulsions. Patients with kidney problems are at increased risk of serious toxicity.

While you are using it

- Things you must do

- Always take your medicine exactly as your doctor has told you.
- Inform all the doctors, dentists and pharmacists treating you that you are taking SALAZINE.
- If you are about to start taking any new medicines, remind your doctor or pharmacist that you are taking SALAZINE.
- Tell your doctor immediately if you become pregnant while taking SALAZINE.
- If you are breastfeeding, stop taking this medicine, once you notice blood in stools or diarrhoea in newborn.
- Ensure you drink plenty of fluids while taking SALAZINE.
- Sulfasalazine may interfere with some medical tests. Your doctor will evaluate your results depending on your symptoms.
- Tell your doctor immediately if you notice any unusual symptoms.

- Things you must not do

- Do not stop taking SALAZINE or change the dose without first checking with your doctor.
- Do not take SALAZINE to treat any other complaint unless your doctor tells you to.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

The effect of sulfasalazine on the ability to drive and use machines has not been evaluated. However, be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

Side effects

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

Stop taking SALAZINE and tell your doctor immediately if you experience any of the following symptoms after taking this

medicine. Although they are 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).
- Severe skin rash that causes blistering (this can affect the mouth or 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.
- Serious skin condition with a rash (sometimes confined to the cheeks and bridge of the nose) with peeling skin or blistering that may be triggered or aggravated by sunlight. Should this occur, stop taking this medicine, avoid strong sunlight and contact your doctor promptly.
- Generally feel unwell, have a fever, have pains in your joints, hives, swollen glands, rash and itching. These may be signs of serum sickness. Your doctor will stop your treatment in these cases.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine:

- 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 SALAZINE while awaiting the results of blood tests.

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 heart (pericarditis).
- Inflammation of heart muscle (myocarditis).
- Bluish tint to skin due to poor circulation.
- Lung complications with breathlessness.
- Inflammation of salivary glands on either side of the face.

- Kidney inflammation, kidney stones and associated 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 back.
- 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.
- 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.

The above is not a complete list of all possible side effects. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SALAZINE

Storage

Store in a cool and dry place, below 30°C.
Keep medicines in original packaging and away from direct heat, light and excessive moisture.
Keep out of the reach and sight of children.

- Disposal

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.

Product Description

- What it looks like

SALAZINE is yellow oval biconvex enteric film coated tablet embossed with "S21" on one side and "SPS" on the other side.

- Ingredients

- Active ingredient
Each tablet contains Sulfasalazine 500mg.

- Inactive ingredients
Microcrystalline cellulose, dicalcium phosphate anhydrous, pregelatinized starch, croscarmellose sodium, corn starch, sodium lauryl sulfate, sodium starch glycolate, crospovidone, colloidal silicon dioxide, talcum, magnesium stearate, hypromellose, polyethylene glycol, methacrylic acid-ethyl acrylate copolymer, sodium hydroxide and simethicone.

- Packing

Blister strip of 10 tablets, pack in box of 50 tablets, 100 tablets and 500 tablets.

- MAL Number

MAL12085066AZ

Manufacturer

Sriprasit Pharma Co., Ltd.
216 Moo 6, Suanluang, Krathum Baen,
Samut Sakhon 74110, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.
No. 5 & 9, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur, Malaysia.

Date of Revision

26/02/2021

Serial Number

NPRA(R2/1)211129/800