Package leaflet: Information for the user

Sulfasalazine

500 mg Tablets

2026-5074-LEA2
FPO

sulfasalazine

Read all of this leaflet carefully before you take 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.

What is in this leaflet:

1. What Sulfasalazine Tablets are and what they are used for
2. What you need to know before you take Sulfasalazine Tablets
3. How to take Sulfasalazine Tablets
4. Possible side effects
5. How to store Sulfasalazine Tablets
6. Contents of the pack and other information

1. What Sulfasalazine Tablets are and what they are used for

The active substance in Sulfasalazine Tablets is sulfasalazine which is an anti-inflammatory drug and belongs to a group of medicines called aminosalicylates.
Your doctor may give you Sulfasalazine Tablets to treat and manage inflammatory bowel disease.

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). Sulfasalazine 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).
Sulfasalazine Tablets 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 take Sulfasalazine Tablets

Your doctor will perform complete blood counts and liver function tests before starting Sulfasalazine 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 Sulfasalazine. For patients with baseline renal impairment, treatment with Sulfasalazine 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 Sulfasalazine. Treatment should be discontinued if renal function deteriorates.

Do not take Sulfasalazine Tablets:

- 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.

Sulfasalazine Tablets 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 Sulfasalazine Tablets, or any other sulfasalazine containing products, because they may affect results of blood and urine tests.

Talk to your doctor or pharmacist before taking Sulfasalazine Tablets:

- 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 Sulfasalazine Tablets, 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 Sulfasalazine Tablets you must not be re-started on Sulfasalazine Tablets at any time. If you develop a rash or these skin symptoms, stop taking Sulfasalazine Tablets, 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 Sulfasalazine Tablets. 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. Sulfasalazine Tablets 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 Sulfasalazine Tablets
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 Sulfasalazine 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 birth defects of the brain, spine or spinal cord, 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.
- methenamine hippurate, this medicine may interact with sulfasalazine and contribute to the formation of crystals in the urine (crystalluria), potentially leading to kidney problems.

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 Sulfasalazine Tablets. If this happens you must stop taking Sulfasalazine Tablets 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.

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

Driving and using machines
Sulfasalazine Tablets are unlikely to affect your ability to drive or use machinery.

3. How to take Sulfasalazine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The tablets should be taken with a glass of water and should be swallowed whole. Do not crush, break or chew the tablets.
The recommended 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-Ups**

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-Ups**

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 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 lifelong condition.

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

If you take more Sulfasalazine Tablets 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 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 forget to take Sulfasalazine Tablets
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 tablet.**

If you stop taking Sulfasalazine Tablets
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.

Stop taking Sulfasalazine 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). 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 Sulfasalazine 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 side-effects (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)
- 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 Sulfasalazine Tablets

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

Store your tablets below 25°C in a dry place.

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

What Sulfasalazine 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.
Sulfasalazine is supplied in bottles. Each bottle contains 112 tablets.

Marketing Authorisation Holder and Manufacturer
The marketing authorisation for this medicine is held by:
Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.
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 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 Sulfasalazine 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.

This leaflet was last revised in 10/2026

Ref: SZ 23_0

Pfizer