



Package leaflet: Information for the user

Sulfasalazine 250mg/5ml Oral Suspension

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 your 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

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1. What Sulfasalazine Suspension is and what it is used for

The active ingredient in Sulfasalazine Suspension is sulfasalazine which is an anti-inflammatory drug and belongs to a group of medicines called aminosalicylates. Your doctor may give you Sulfasalazine 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 is used to control the flare-ups of ulcerative colitis. It 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 is 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 Suspension

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:

- if you are allergic (hypersensitive) to any of the ingredients of Sulfasalazine Suspension
- if you 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.

Sulfasalazine should **not be used in children under 2 years** of age.

Warnings and precautions

Tell your doctor if you are taking or have recently taken Sulfasalazine, 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:

- 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, 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 you must not be re-started on Sulfasalazine at any time. If you develop a rash or these skin symptoms, stop taking Sulfasalazine, 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. 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 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

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:

- 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.

Sulfasalazine Suspension with food and drink

Sulfasalazine Suspension should be taken with or after food.

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. If this happens you must stop taking Sulfasalazine 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 is unlikely to affect your ability to drive or use machines.

Sulfasalazine Suspension contains:

- This medicine contains 5 mg sodium benzoate in each 5ml.
- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

3. How to take Sulfasalazine Suspension

The suspension should be taken with food. The doses should be evenly divided during the day. Unless your doctor has told you otherwise, the usual doses for the following conditions are:

Ulcerative Colitis and Crohn's Disease

Adults and the Elderly

Severe flare-ups: 20-40 ml four times a day, with other medicines such as steroids. Do not leave more than 8 hours between the evening and the following morning dose.

Mild/Moderate flare-ups: 20-40 ml four times a day, but not always with other medicines

Ulcerative Colitis

Maintenance: Once the flare-up is controlled the dose is slowly reduced to 40 ml 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.

How long should you use Sulfasalazine?

This depends on how well the suspension suits you. The suspension starts to work in a few days. If it works well, you may be using it for some time. Do not stop using the suspension just because you feel better without first 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 Sulfasalazine than you should

Contact your nearest hospital casualty department or tell your doctor immediately, if you have taken too much suspension or if a child has taken your medicine.

Please take this leaflet and the suspension with you to the hospital casualty department or to your doctor.

If you forget to take Sulfasalazine

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

4. Possible side effects

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

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

- 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). 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 immediately.
- 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.
- If you are breast feeding stop taking this medicine, once you notice blood in stools or diarrhoea in newborn.

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 as they will stop treatment in these cases:

- If you notice any unexplained bleeding

- If you notice bruising, fever, rash pallor (paleness), severe sore throat or tiredness.

These may be the first signs of an abnormality of the blood, including decreases in the number of red and white blood 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 (may affect more than 1 in 10 people):

- dizziness
- headache
- changes in taste
- ringing in ears
- cough
- itching of the skin
- purple discolourations on the skin
- protein in urine
- abdominal (stomach) pain
- joint pain
- difficulty sleeping
- fever
- diarrhoea
- loss of appetite
- being sick
- inflamed mouth (stomatitis)
- blood shot eyes and eye infections.

Uncommon (may affect more than 1 in 100 people):

- depression
- fits, jerky, uncontrolled movements
- shortness of breath
- hair loss
- hives
- puffiness around the eyes and face
- loss of balance
- yellowing of the skin or whites of the eyes (jaundice)

Not known (frequency cannot be estimated from the available data)

- tingling, numbness, pains in hands and feet
- fits, jerky uncontrolled movements
- hallucinations
- inflammation of the lining of the brain

- inflammation of the sac surrounding the heart (pericarditis)
- severe diarrhoea
- changes in smell
- change in mental state
- inflammation of the salivary glands on either side of the face
- inflammation of the heart muscle (myocarditis)
- bluish tint or paleness to skin due to poor circulation
- inflammation of the pancreas, which causes severe pain in the abdomen and face
- blood vessel inflammation
- blood and crystals in urine
- urine or motions may become a yellow/orange colour which is normal and harmless. (See section 6).
- lung complications with breathlessness
- rash, reddening or blistering of the skin, eczema, swelling of the skin
- kidney inflammation and kidney pain, kidney stones
- liver disease (hepatitis)
- temporary infertility in men. Fertility returns when treatment is stopped. Normal contraception should still be used
- other blood disorders including anaemia and enlarged glands (lymph nodes), glandular fever, persistent sore throat
- 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 or pharmacist. 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 Suspension

- Keep out of the sight and reach of children.
- Do not use Sulfasalazine Suspension after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month. Take back to the pharmacy 1 month after you first open it.
- Store your medicine below 25°C in a dry place.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sulfasalazine Suspension contains

The active substance is sulfasalazine. Each 5ml of suspension contains 250mg of the active ingredient sulfasalazine.

The other ingredients are xanthan gum (E415), dispersible cellulose, acesulfame K (E950), lemon flavour, polysorbate 80, sodium benzoate (E211), citric acid monohydrate (E330), sodium citrate (E331) and water.

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.

What Sulfasalazine Suspension looks like and contents of the pack

The suspension is orange/yellow in colour, with lemon flavour. The medicine comes in a brown glass bottle which contains 500ml of suspension. The suspension is the colour of the medicine itself. Contains no artificial colouring.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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