

Consumer Medicine Information

What is in this leaflet

"Salazopyrin" will be used in this leaflet to refer to the "plain" and "EN" tablets unless specified.

This leaflet answers some common questions about Salazopyrin.

It does not contain all the available information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Salazopyrin against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Salazopyrin is used for

What Salazopyrin does

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

Salazopyrin EN tablets are also used to treat rheumatoid arthritis, which is a painful joint disease.

Salazopyrin EN tablets help prevent damage to your joints. It works to slowly reduce the swelling and stiffness in your joints. It is usually given when a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) are not working.

How Salazopyrin works

The active substance in Salazopyrin is sulfasalazine. It has a number of effects in the body. It is an immunosuppressive and an anti-inflammatory medicine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Salazopyrin is available only with a doctor's prescription.

There is no evidence that Salazopyrin is addictive.

Before you take Salazopyrin

When you must not take it

Do not take Salazopyrin if you have an allergy to:

- sulfasalazine
- sulfur-containing medicines e.g. sulfonamides; some oral hypoglycaemics (diabetes medicine) e.g. glipizide; thiazide diuretics e.g. chlorothiazide
- salicylates e.g. aspirin
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you are not sure if you have or have had an allergic reaction to Salazopyrin, check with your doctor.

Do not take Salazopyrin if you are taking the following medicines:

- sulfur-containing medicines e.g. sulfonamides; some oral hypoglycaemics (diabetes medicine) e.g. glipizide; thiazide diuretics e.g. chlorothiazide
- salicylates e.g. aspirin.

Do not take Salazopyrin if you have the following medical conditions:

- kidney or liver problems
- any form of blood disorder
- any form of intestinal or urinary obstruction
- porphyria (rare disease of blood pigments).

If you are not sure about any of the above, ask your doctor.

Do not take Salazopyrin if:

- the packaging is torn or shows signs of tampering or the tablets do not look quite right
- the expiry date (Exp.) on the carton has passed.
If you take this medicine after the expiry date has passed, it may not work as well.

Do not give Salazopyrin to children under two years of age.

Do not take Salazopyrin to treat any other complaints unless your doctor says to.

See your doctor for a check up before you start to take Salazopyrin.

Before you start taking Salazopyrin

Tell your doctor if you:

- are pregnant or trying to become pregnant
- are breast feeding or plan to breast-feed. Your doctor will discuss the possible risks and benefits of taking Salazopyrin during pregnancy and breast-feeding.
- are allergic to any other medicines or any other substances such as foods, preservatives or dyes
- have a glucose-6-phosphate dehydrogenase (G-6-P) deficiency. This is a rare blood disorder which means that your body cannot get rid of some medicines
- have bronchial asthma (wheezing or shortness of breath)
- have a history of recurring or chronic infections.

If you have not told your doctor about any of the above, tell him/her before you start taking Salazopyrin.

Your doctor will send you to have blood tests to help assess your liver and kidney function and the levels of various cells in your bloodstream before you start treatment with Salazopyrin. You may also have a urine test to monitor your kidney function.

Your doctor will also send you to have the tests repeated at various times during your treatment with Salazopyrin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

There may be interference between Salazopyrin and some other medicines including:

- oral medicines used to prevent blood clots e.g. warfarin
- methotrexate, a medicine used to treat arthritis and some cancers
- medicines to lower blood sugar or control diabetes
- mercaptopurine and azathioprine, medicines used to treat some cancers
- antacids, medicines that help to control heartburn or symptoms of indigestion
- digoxin, a medicine used to treat heart failure
- oxyphenbutazone, phenylbutazone, indomethacin and sulfinpyrazone which are medicines used to treat arthritis and gout
- salicylates, a medicine used to treat minor relief of pain e.g. aspirin
- oxacillin and penicillins, which are types of antibiotics
- certain local anaesthetics
- medicines used to make the urine more acidic
- iron tablets.

These medicines may be affected by Salazopyrin or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Salazopyrin.

How to take Salazopyrin

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Inflammatory Bowel Disease

Salazopyrin tablets are usually taken after meals at evenly spaced intervals over a 24 hour period.

Adults: the usual initial dose is 2 to 4 tablets, four times a day. The usual maintenance dose is 4 tablets a day.

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

Rheumatoid Arthritis

Adults: the usual dose is 2 Salazopyrin EN tablets, two to three times a day. It is usual to start taking Salazopyrin EN tablets at a lower dose and gradually increase. Your doctor will

advise whether you should do this and how to do this.

Salazopyrin EN is not recommended for treating rheumatoid arthritis in children.

How to take it

Salazopyrin should be swallowed whole after meals with a full glass of water.

It is important to maintain adequate fluid intake while taking Salazopyrin.

Do not crush, break or chew Salazopyrin EN tablets.

How long to take it

Continue taking Salazopyrin for as long as your doctor recommends.

If you forget to take it

If you forget to take your Salazopyrin, take your next dose at the normal time it is due.

Do not try to make up for missed doses by taking more than one dose at a time because this may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (in Australia, phone 13 11 26; in New Zealand, phone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much Salazopyrin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptoms of taking too many Salazopyrin tablets may include stomach discomfort and other effects listed under the heading "Side effects" in this leaflet.

While taking Salazopyrin

Things you must do

Advise your doctor immediately if you notice any unusual symptoms.

Ensure you drink plenty of fluids while on Salazopyrin.

Tell your doctor immediately if you become pregnant while taking Salazopyrin.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Salazopyrin.

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are taking Salazopyrin.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Tell your doctor that you are taking this medicine if you are about to have any blood or urine tests.

It may interfere with the results of some tests.

Make sure that you keep all doctor's appointments for check-ups and any tests that your doctor may order for you while you are taking Salazopyrin.

Protect your skin when you are in the sun, especially between 10am and 3pm. Salazopyrin may cause your skin to be more sensitive to sunlight than it is normally. If outdoors, wear protective clothing and use a

15+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

Things you must not do

Do not take Salazopyrin to treat any other complaints unless your doctor tells you to.

Do not stop taking Salazopyrin or change the dose without first checking with your doctor.

Do not give Salazopyrin to anyone else even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Salazopyrin affects you.

This medicine may cause dizziness or hallucinations in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side Effects

Check with your doctor as soon as possible if you have any concerns while taking Salazopyrin, even if you do not think the concerns are connected with the medicine or are not listed in this leaflet.

All medicines can have side effects and Salazopyrin may have unwanted side effects in a few people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if...

Tell your doctor if you notice any of the following and they worry you:

- nausea and vomiting
- loss of appetite
- raised temperature
- sore throat
- enlarged glands
- diarrhoea
- stomach pains
- headache
- dizziness
- change in sense of smell or taste
- insomnia
- depression
- ringing in the ears
- hallucinations
- increased sensitivity to light
- cough.

If these effects do not go away or they are worrying to you, tell your doctor.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- breathlessness
- chest pain
- palpitations
- redness and itchiness of the skin
- convulsions
- allergic reactions
- swelling of the face
- dermatitis

- loss of hair
- signs of liver disease such as yellowing of skin and eyes and dark coloured urine
- severe pain in the loins or pain on urination.

The above list includes serious side effects that may require medical attention.

Go to hospital if...

If you get a sore throat, fever, pallor, rash and yellow skin tell your doctor immediately. This may mean that you have a serious blood disorder and need urgent medical care.

Other side effects not listed above may also occur in some people. These can only be found when your doctor does tests. These include blood cell changes, reversible low sperm count, swelling of the pancreas, swelling in the mouth, impaired folic acid absorption, peripheral neuropathy and neuritis (which cause tingling, burning or numbness in the hands or feet), changes in kidney function and lung complications.

The above is not a complete list of all possible side effects. Some people may get other side-effects while taking Salazopyrin.

It is very important to tell your doctor immediately if you notice any side-effects while taking Salazopyrin.

It is also important to keep all doctor's appointments.

After taking Salazopyrin

Storage

Keep your tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Your Salazopyrin tablets should be stored in their original container in a cool, dry place where the temperature stays below 25°C.

If you take your tablets out of their bottle, they may not keep as well. Make sure the container is closed after use.

Do not store Salazopyrin or any other medicine in a bathroom or near a sink. Do not leave them in the car or on window sills. Heat and dampness can destroy medicines.

Disposal

If your doctor tells you to stop taking Salazopyrin, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product Description

What Salazopyrin looks like

Salazopyrin tablets are yellow-orange, round and scored tablets, marked with '101' on one side and 'KPh' on the other side. They come in plastic bottles containing 100 tablets.

Salazopyrin EN tablets are enteric coated 500mg tablets. They are yellow-orange, elliptical convex tablets, marked with '102' on one side and 'KPh' on the other side. Salazopyrin EN 500 mg tablets come in plastic bottles containing 100 tablets.

Ingredients

Salazopyrin tablets contain 500 mg sulfasalazine per tablet.

It also contains silica, magnesium stearate, maize starch.

Salazopyrin EN tablets contain 500 mg sulfasalazine per tablet. It also contains

silica, magnesium stearate, maize starch, cellulose, propylene glycol, white beeswax, carnauba wax, glyceryl monostearate, macrogol 20000 and talc.

Salazopyrin tablets do not contain lactose, sucrose, or tartrazine.

Supplier

Salazopyrin is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia.

Toll Free Number: 1800 675 229.

Salazopyrin is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland, New Zealand.

Toll Free Number: 0800 736 363.

Australian Registration Number

500 mg tablets: AUST R 14486

500 mg EN tablets: AUST R 14485.

Date of preparation

This leaflet was revised in July 2016.

© Pfizer Australia Pty Ltd 2016

® Registered trademark