

SALAZOPYRIN(R)

tablets and EN tablets

Sulfasalazine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Salazopyrin tablets or Salazopyrin EN tablets. This leaflet answers some common questions about Salazopyrin (when this name is used it will refer to both the plain and EN tablets unless specified).

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.

Use Salazopyrin as instructed and follow the advice given in this leaflet.

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

Salazopyrin belongs to a group of medicines called anti-inflammatory medicines and is used to treat and manage Ulcerative Colitis and Crohn's disease which are diseases of the bowel.

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

Salazopyrin is available only with a doctor's prescription.

There is no evidence that Salazopyrin is addictive.

Before you take Salazopyrin

Some information is provided below. However, always talk to your doctor if you have concerns or questions about your treatment.

When you must not take Salazopyrin

Do not take Salazopyrin if you have an allergy to:

- * sulfur-containing medicines eg. sulfonamides; some oral hypoglycaemics (diabetes medicine) eg. glipizide; thiazide diuretics eg. Chorothiazide
- * salicylates eg. aspirin
- * any of the ingredients of Salazopyrin which are listed under the heading, "Product Description", at the end of this leaflet.

Symptoms of an allergic reaction to Salazopyrin may include skin rash and itching, breathlessness and anaphylactic reactions (major allergic reactions).

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

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

- * 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 use Salazopyrin to treat any other complaints unless your doctor says so.

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)

Taking other medicines

Tell your Doctor 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 eg. 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
- * 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

How to take Salazopyrin

Your doctor will tell you how to take Salazopyrin. The directions your doctor gives you should be strictly followed. The directions given to you by your doctor may differ from the information contained in this leaflet. You may be given a different dosage depending on your condition and how you react to this medicine.

Salazopyrin should be swallowed after meals with water.

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

Do not crush, break or chew Salazopyrin EN tablets.

How much to take and when to take it

Inflammatory Bowel Disease

Salazopyrin tablets should be taken after meals in evenly spaced doses over each 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.

At present there is no dose recommendation for treating rheumatoid arthritis in children.

How long to take Salazopyrin

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 (telephone 13 11 26) 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. Keep telephone numbers for these places/services handy. Have the Salazopyrin bottle or this leaflet available to give details if needed.

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 if you become pregnant while taking Salazopyrin.

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

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

Ensure 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 a severe sunburn.

Things you must not do

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.

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 you notice any of the following and they worry you:

- * nausea and vomiting
- * loss of appetite
- * raised temperature
- * fever
- * redness and itchiness of the skin
- * diarrhoea
- * stomach pains
- * swelling of the liver
- * headache
- * dizziness
- * abnormal change in sense of smell or taste
- * insomnia
- * depression
- * convulsions
- * ringing in the ears
- * hallucinations
- * yellow skin
- * allergic reactions
- * skin rash
- * dermatitis
- * loss of hair
- * increased sensitivity to light
- * breathlessness
- * cough

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

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.

Salazopyrin can also cause:

blood cell changes, low sperm count (which is reversible), pancreatitis (swelling of the pancreas), stomatitis (swelling in the mouth), impaired folic acid absorption, peripheral neuropathy and neuritis (which cause tingling, burning or numbness in the hands or feet), kidney changes and lung complications.

This 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.

After treatment with Salazopyrin

Storage

Keep your tablets where children cannot reach them.

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

If you take your tablets out of their bottle, they may not keep as well. Make sure the container is well 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, round, scored and marked '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, oval, and marked with '102' on one side and 'KPh' on the other side. Salazopyrin EN 500mg tablets come in plastic bottles containing 100 tablets.

Identification

Salazopyrin tablets can be identified by an Australian Register number which is found on the bottle label:

500 mg tablets: AUST R 14486

500 mg EN tablets: AUST R 14485

Ingredients

The active ingredient in each tablet is sulfasalazine. Each tablet contains 500mg sulfasalazine.

Salazopyrin tablets also contain:

silica, magnesium stearate, maize starch.

Salazopyrin EN tablets also contain:

silica, magnesium stearate, maize starch, cellacephate, 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

This leaflet was revised in March 2006

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