

### PART III: CONSUMER INFORMATION

#### PrSALAZOPYRIN<sup>®</sup> and SALAZOPYRIN EN-tabs<sup>®</sup> (sulfasalazine and sulfasalazine delayed-release tablets)

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Salazopyrin<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

SALAZOPYRIN<sup>®</sup> contains sulfasalazine, which is an anti-inflammatory drug indicated as an adjunctive therapy in the treatment of severe ulcerative colitis (bowel inflammation), proctitis (inflammation of the rectum) or distal ulcerative colitis and Crohn's disease.

SALAZOPYRIN EN-tabs<sup>®</sup> contains sulfasalazine in delayed-release tablets, indicated for the treatment of active rheumatoid arthritis, when treatment with an adequate conventional first line therapy has failed.

##### What it does:

The way in which SALAZOPYRIN works is unclear and thought to involve three actions:

- anti-inflammatory action, which blocks the production and effect of certain substances in the body (cyclooxygenase, prostaglandins and others), which are involved in producing inflammation;
- bacteriostatic (anti-bacterial) action, which prevents the growth of several kinds of bacteria which are possibly involved in inflammation;
- immunosuppressive action (which reduces a patient's overly active immune response, which has been linked to inflammatory diseases).

All of these actions likely work together to reduce symptoms of gut inflammation, diarrhea, swelling and bleeding.

##### When it should not be used:

Do not use SALAZOPYRIN if you have:

- a hypersensitivity (allergic reactions) to sulfasalazine, its metabolites, sulfonamides, salicylates or any other component of this product ( see What the non-medicinal ingredients are);
- an intestinal or urinary obstruction;
- porphyria (disease of pigment production in tissues).
- experienced sudden asthmatic attacks, urticaria, rhinitis, or other allergic-type reactions to acetylsalicylic acid or other nonsteroidal anti-inflammatory, as these attacks are serious and can be fatal (see **WARNINGS AND PRECAUTIONS** for a complete list of conditions where SALAZOPYRIN should not be used);
- severe kidney (renal) impairment and/or severe liver (hepatic) impairment (see Side Effects and What to Do About Them)

This drug is not to be used in infants under 2 years of age.

##### What the medicinal ingredient is:

Sulfasalazine

##### What the nonmedicinal ingredients are:

SALAZOPYRIN tablets contain: pregelatinized starch, magnesium stearate, colloidal silicon dioxide

SALAZOPYRIN EN-tabs contain: pregelatinized starch, magnesium stearate, colloidal silicon dioxide, cellulose acetate phthalate, propylene glycol, beeswax white, carnauba wax, polyethylene glycol 20 000, self-emulsifying glyceryl monostearate, talc

##### What dosage forms it comes in:

SALAZOPYRIN is available as`

- SALAZOPYRIN tablets: each 500 mg tablet is yellow-orange, round, convex and engraved with the letters KPh on one side and with 101 and a score line on the other side. Supplied in bottles of 100 and 300.
- SALAZOPYRIN EN-tabs, Delayed-release Tablets: each long-acting 500 mg tablet is yellow-orange elliptical, convex and engraved with the letters KPh on one side and with 102 on the other side. Supplied in bottles of 100 and 300.

#### WARNINGS AND PRECAUTIONS

**BEFORE you use SALAZOPYRIN talk to your doctor or pharmacist if you:**

- have had any allergic reactions to any sulfonamides, furosemide or thiazide diuretics (water pills), dapsone, sulfoxone, oral hypoglycemics (diabetes drugs you take by mouth), glaucoma medicines you take by mouth (for example, acetazolamide, dichlorophenamide, methazolamide), or salicylates (for example, acetylsalicylic acid);
- are pregnant or intend to become pregnant while taking this medicine;
- are breastfeeding an infant. Sulfonamides pass into the breast milk in small amounts and may cause unwanted effects in infants with glucose-6-phosphate dehydrogenase (G6PD) deficiency. There have been reports of bloody stools or diarrhea in infants who were breastfeeding from mothers on sulfasalazine.
- intend to father a child (low sperm count);
- have any of the following medical problems:
  - Blockage of the stomach, intestines, or urinary tract
  - Blood problems
  - Glucose-6-phosphate dehydrogenase (G6PD) deficiency
  - Kidney disease
  - Liver disease
  - Porphyria

- History of recurring or chronic infections. If you develop a new infection while taking SALAZOPYRIN, talk to your doctor.
- are now taking any other medicines (See Interactions with this medicine).
- before having any kind of surgery, including dental surgery, with a general anaesthetic, tell the physician or dentist in charge that you are taking a sulfonamide.

- Thiopurine 6-mercaptopurine
- Trioxsalen
- Vitamin K

Drug interactions with antibiotics, anticoagulants, coumarin- or indandione-derivative, anticonvulsants, oral antidiabetic agents, digitalis glycosides or folic acid, methenamine, methotrexate, oxyphenbutazone or phenylbutazone, photosensitizing medications, probenecid, sulfapyrazone, thiopurine methyltransferase (TPMT) are possible.

Sulfasalazine may interfere with some medical tests. Your healthcare provider will evaluate your results depending on your symptoms.

Stop taking SALAZOPYRIN immediately and tell your doctor if you develop the following symptoms:

- Skin rash, fever, swollen lymph nodes, lesions inside your mouth or nose;
- Sore throat, fever, pallor (pale skin), swollen lymph nodes, purple discoloration of the skin which does not blanch under pressure or jaundice (yellowing of your skin or white porting of your eye).

**Do not give this medication to infants under 2 years of age.**

## INTERACTIONS WITH THIS MEDICATION

If taken with some other medicines, the effects of SALAZOPYRIN or the other medications may change. Please check with your doctor or pharmacist before taking any other medications with SALAZOPYRIN such as:

- Anthralin
- Antibiotics
- Anticoagulants, coumarin- or indandione-type (blood thinners)
- Antidiabetic agents, oral (diabetes medicines you take by mouth)
- Azathioprine
- Coal tar
- Dapsone
- Digitalis glycosides (heart medicine)
- Dipyrone
- Diuretics (water pills or high blood pressure medicine)
- Ethotoin
- Folic acid
- Furazolidone
- Mephenytoin
- Methenamine
- Methotrexate
- Methoxsalen
- Nalidixic acid
- Nitrofurantoin
- Other sulfonamides
- Oxyphenbutazone
- Phenothiazines (tranquilizers)
- Phenylbutazone
- Phenytoin
- Primaquine
- Probenecid
- Sulfapyrazone
- Sulfoxone
- Tetracyclines

## PROPER USE OF THIS MEDICATION

### Usual adult dose:

Take SALAZOPYRIN as directed by your doctor, at regular and even intervals over the 24 hour period. If you are taking SALAZOPYRIN tablets for an intestinal inflammatory disease, the night-time doses interval should not exceed 8 hours.

SALAZOPYRIN tablets (sulfasalazine) are best taken after meals or with food to lessen stomach upset. If stomach upset continues or is bothersome, check with your doctor.

**Each dose of SALAZOPYRIN should also be taken with a full glass (8 ounces) of water. Several additional glasses of water should be taken every day,** unless otherwise directed by your doctor. Drinking extra water helps prevent unwanted side effects of the sulfonamide.

For patients taking the delayed-release tablet form of this medicine:

- Swallow tablets whole. Do not break or chew.
- Contact your doctor if you notice any undisintegrated tablet in your stool.

**Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days. Do not miss any doses.**

If your symptoms (including diarrhea) do not improve within a month or two or if they become worse, check with your doctor. It is important that your doctor check your progress at regular visits.

Laboratory and blood tests may be scheduled for you by your doctor before and during treatment.

### Overdose:

If you think you have taken too much SALAZOPYRIN, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

### Missed Dose:

If you do miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, **do not** take the missed dose or double your next dose. Instead, go back to your regular dosing schedule.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects appear very often, when they do occur they may require medical attention.

Other side effects (than those mentioned in the following table) may occur, which usually do not require medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

More Common: Diarrhea, dizziness, loss of appetite, nausea or vomiting, headache, itching, skin rash, upset stomach.

Less Common: rash, itching, hives, fever.

Rare: blood problems

In some patients this medicine may also cause the urine to become orange-yellow, or may stain contact lenses yellow. This side effect does not require medical attention.

Some people who take sulfonamides may become more sensitive to sunlight than they are normally. When you begin to take this medicine, avoid too much sun or too much use of a sunlamp until you see how you react, especially if you tend to burn easily. You may still be more sensitive to sunlight or sunlamps for many months after you stop taking this medicine. If you have a severe reaction, check with your doctor.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
<b>More common</b>	Low sperm counts (oligospermia), with infertility, have been observed with men taking Salazopyrin, which is reversible within several months of stopping the medication.			√
	Increased sensitivity of the skin to sunlight		√	

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
<b>Less Common</b>	Aching in joints and muscles, difficulty in swallowing, fever, pale skin, redness, blistering, peeling or loosening of the skin, sore throat, unusual bleeding or bruising, unusual tiredness or weakness, yellowing of the eyes or skin, mouth sores, ringing in the ears			√
<b>Rare</b>	<ul style="list-style-type: none"> <li>- Kidney problems with symptoms such as blood in the urine, lower back pain, pain or burning when urinating, swelling of the front part of the neck</li> <li>- Liver problems including liver failure, with symptoms such as abdominal pain, nausea, yellowing of the eyes or skin</li> <li>- Interstitial lung disease with symptoms such as shortness of breath and difficulty breathing</li> <li>- Hypersensitivity (allergic) reactions including death with symptoms such as rash, swelling of the mouth, throat, lips, other tissues, and difficulty in breathing</li> </ul> These symptoms have been associated with Salazopyrin use			√

*This is not a complete list of side effects. For any unexpected effects while taking SALAZOPYRIN®, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store at 15-30°C. Keep out of reach and sight of children.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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