Patient package insert in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Salazopyrin®
Tablets

Salazopyrin® EN
Enteric-coated tablets

Each tablet contains sulfasalazine 500 mg
For a list of inactive and allergenic ingredients in the preparation, please see section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- Treatment of ulcerative colitis and Crohn's disease.
- Salazopyrin® EN enteric-coated tablets are also used for treatment of rheumatoid arthritis and inflammatory skin ulcers (pyoderma gangrenosum).

Therapeutic group:
Anti-inflammatory drug of aminosalicylic acid type.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine:

× If you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine, to salicylates (such as aspirin) or to sulfonamides (a certain type of antibiotic).
× If you have a disease known as porphyria (a rare blood system disorder).
× **In children under the age of two years.**

Special warnings regarding the use of the medicine
! Before treatment with Salazopyrin®, tell the doctor:
- If you have a deficiency of the G6PD enzyme which is responsible for normal function of red blood cells.
- If you have or have ever had asthma.
- If you have or have ever had impaired function of the liver or the kidney.
- If you have or have ever had impaired function of the blood system (such as coagulation).
- If you have or have ever had an acute allergy.
- In case of treatment of rheumatoid arthritis in children.

Folic acid deficiency may occur during treatment with the medicine, which may lead to a blood system disorder; this can be prevented by taking folic acid or folinic acid (leucovorin).

! Tests and follow up
! The doctor will refer you to complete blood count and liver function test before you start treatment with the medicine and once in two weeks during the first three months of treatment, once a month during the next three months of treatment and afterwards, every three months and as required.
! The medicine may affect certain laboratory tests results, such as liver enzymes, e.g. alanine transaminase (ALT). If you notice a deviation, consult the doctor.
! The doctor will refer you to urine test and assessment of kidney function before you start treatment and at least once a month during the first three months of treatment, and then as required.
! You should inform the doctor immediately if you experience symptoms such as sore throat, fever, pallor, skin rash caused by bleeding from small blood vessels (purpura), jaundice, malaise or appearance of unexpected illness.
! Stop taking the medicine immediately while you are waiting for blood test results.

! Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- medicines for treatment of high blood sugar levels/diabetes. This may result in a decrease in sugar level; patients taking these medicines should be under medical supervision.
- methenamine, an antibiotic for treatment of urinary tract infections.
- digoxin, for treatment of heart disease. This may result in reduced medical efficacy of digoxin.
- folate (such as folic acid) given during pregnancy.
- azathioprine and mercaptopurine – used after organ transplantation and in chronic inflammations such as rheumatoid arthritis.
- methotrexate (to treat rheumatoid arthritis). This may result in an increased frequency of gastrointestinal side effects, especially nausea.

! Using of the medicine and food
The medicine should be taken with or after food.

! Pregnancy, breast-feeding and fertility
Pregnancy and breast-feeding
If you are pregnant or breast-feeding, planning to become pregnant or to breast-feed, ask your doctor for advice before taking this medicine. You should avoid breast-feeding the baby during treatment with the medicine. There have been reports of diarrhea or bloody stools in babies of breast-feeding mothers taking the medicine. These symptoms have resolved after the mother has stopped taking the medicine.

Fertility
The medicine may cause a disorder in sperm production and temporary male infertility. This effect is reversible within two to three months of discontinuation of the treatment with the medicine.

! Driving and using machines
Use of the medicine is unlikely to affect the ability to drive or use of machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

Swallow the medicine whole with a glass of water.

Do not crush/split/chew the tablets:
since the tablets are film-coated (Salazopyrin® EN).
since the effects of these modes of administration has not been examined (Salazopyrin®).

Make sure that you are drinking a sufficient amount of fluids while taking the medicine to avoid kidney problems.

Refer to a doctor if the film-coated tablet (Salazopyrin® EN) remained intact in stool, since in such case the active ingredient has not been absorbed.

If you accidentally take a higher dosage
If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you forgot to take this medicine at the designated time, take the next dose at the usual time. Do not take a double dose to make up for the forgotten dose.

Persist with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of the medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop the treatment and refer to a doctor immediately if you experience any of the following symptoms after taking the medicine. Although these symptoms are very rare, they may be serious.
- An allergic reaction including wheezing, difficulty breathing, swelling of eyelids, face or lips, rash or itching (especially when affecting the whole body).
- If you develop an acute skin rash that causes blistering (this may affect the mouth and tongue). These may be signs of Stevens-Johnson syndrome, or toxic epidermal necrolysis (TEN). The doctor will stop the treatment in these cases.
- If you have serious skin problems 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 refer to a doctor immediately**.
- If you are generally feeling unwell, have a fever, have pain in your joints, hives, swollen glands, rash and itching. These may be signs of a condition known as serum sickness. The doctor will stop the treatment in these cases.
- If you are breast-feeding, **stop taking this medicine** once you notice blood in stools or diarrhea in the newborn.

Tell the doctor immediately if you experience any of the following symptoms after taking this medicine, as he may stop treatment in the following cases:
- If you notice any unexplained bleeding.
- If you notice bruising, fever, rash, pallor, a severe sore throat or tiredness.

These may be the first signs of a blood problem, including decrease in the number of red blood cells, white blood cells and platelets. Your doctor will perform routine blood tests to check for these effects.

Discontinue treatment with the medicine while waiting for the blood test results.

Additional side effects that may occur are:
Very common side effects (may appear in more than 1 in 10 people) including:
- Indigestion, heartburn
- Nausea

Common side effects (may appear in more than 1 in 100 people) including:
- Dizziness
- Difficulty sleeping
- Headache
- Changes in taste
- Abdominal pain
- Diarrhea
- Vomiting
- Ringing in the ears
- Red eyes
- Inflamed oral mucosa (stomatitis)
- Cough
- Itching of the skin
- Joint pain
- Protein in urine
- Fever

Uncommon side effects (may appear in more than 1 in 1000 people) including:
- Depression
- Convulsions, involuntary movements
- Loss of balance
- Shortness of breath
- Hair loss
- Hives
- Swelling around the eyes and in the face

Side effects of unknown frequency (the frequency of these effects has not been established yet):
- Inflammation of the lining of the brain (Meningitis)
- Severe diarrhea
- Blood system disorders including anemia, enlarged lymph nodes
- Blood vessel inflammation
- Loss of appetite
- Hallucinations
- Changes in mental state
- Disorders in sense of smell
- Inflammation of the sac surrounding the heart (pericarditis)
- Inflammation of the heart muscle (myocarditis)
- Bluish tint of the skin due to problems with blood flow
- Lung complications with shortness of breath
- Inflammation of the salivary glands on both sides of the face
- Kidney inflammation and kidney pain
- Liver disease (hepatitis)
- Yellowing of the skin and whites of the eyes (jaundice)
- Inflammation of pancreas (accompanied by severe pain in the abdomen and face)
- Rash, reddening or blistering of the skin, eczema
- Tingling, numbness, pain in the extremities
- Blood in urine
- Urine or stool may become yellow/orange, which is normal and harmless
- Decrease (reversible) in sperm concentration and infertility in men. This effect resolves when treatment with the medicine is stopped. Use of contraception should be continued.

Very rarely, this medicine may cause discoloration of soft contact lenses.

If a side effect has appeared, if one of the side effects gets worse, or when you suffer from a side effect that has not been mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.
- In a bottle pack, after first opening, the medicine can be used for 6 months while stored at room temperature below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Salazopyrin®:
Starch pregelatinized, povidone, magnesium stearate, silica colloidal anhydrous.

Salazopyrin® EN:
Starch pregelatinized, povidone, magnesium stearate, silica colloidal anhydrous, cellulose acetate phthalate, propylene glycol, talc, macrogol, carnauba wax, glyceryl monostearate, beeswax white.

What the medicine looks like and the contents of the package:
Salazopyrin®: A round yellow - orange tablet with "Kph" embossed on one side and "101" on the other side.
Salazopyrin® EN: A film-coated elliptical yellow - orange tablet with "Kph" embossed on one side and "102" on the other side.

The medicine is marketed in packs of bottles containing 100 or 300 tablets or in blisters containing 30 or 100 tablets.

Not all pack sizes may be marketed.

Registration holder's name and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Manufacturer's name and address: Recipharm Uppsala AB, Uppsala, Sweden.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Salazopyrin®: 113-35-21579
Salazopyrin® EN: 113-34-20570

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