PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SALAZOPYRIN EN 500 mg tablets

Sulphasalazine

Sugar free

Read all of this leaflet carefully before you start taking SALAZOPYRIN EN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SALAZOPYRIN EN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SALAZOPYRIN EN is and what it is used for
2. What you need to know before you take SALAZOPYRIN EN
3. How to take SALAZOPYRIN EN
4. Possible side effects
5. How to store SALAZOPYRIN EN
6. Contents of the pack and other information

1. What SALAZOPYRIN EN is and what it is used for

SALAZOPYRIN EN is used in the treatment of acute ulcerative colitis and the maintenance of remission in ulcerative colitis. SALAZOPYRIN EN is also used for the treatment of acute Crohn's disease and the treatment and control of rheumatoid arthritis.

2. What you need to know before you take SALAZOPYRIN EN

Do not take SALAZOPYRIN EN

- if you are hypersensitive (allergic) to sulphasalazine or any of the other ingredients of SALAZOPYRIN EN (listed in section 6).
- if you suffer from porphyria (a disorder that causes nerve or skin problems)
- if you suffer from abnormal bleeding
- if you have severe kidney or liver failure
- if you have a gastric or duodenal ulcer
- if you are pregnant or breastfeeding
- SALAZOPYRIN EN must not be given to infants and children.

Warnings and precautions

Your doctor will perform complete blood counts and liver function tests before starting SALAZOPYRIN 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 be done initially and at least monthly for the first three months of treatment with SALAZOPYRIN EN. Thereafter, monitoring will be performed as clinically indicated.

Take special care with SALAZOPYRIN EN

- if you have a history of recurring or chronic infections or if you develop a new infection while taking SALAZOPYRIN EN, tell your doctor immediately as SALAZOPYRIN EN may need to be discontinued
- if you have problems with your liver or kidney function
- if you suffer from allergies or bronchial asthma
- if you suffer from severe allergic reactions that can harm organs in your body such as the liver, kidneys, heart, or lungs, or have symptoms like mononucleosis, a common viral infection that can make you feel extremely tired and weak, discontinue treatment and contact your doctor immediately
- if you suffer from serious skin reactions, discontinue treatment and contact your doctor

immediately

- if you do not have sufficient folic acid in your body, SALAZOPYRIN EN can have serious effects on your blood
- if you suffer from conditions where your red blood cells function abnormally
- if you do not drink adequate fluids you may risk the chance of crystalluria (crystals in the urine)
- if you suffer from infertility (males) and low sperm count, SALAZOPYRIN EN may increase this incidence
- if you wear contact lenses as SALAZOPYRIN EN may stain them yellow
- if you have HIV, you may experience increased side effects including rash, fever and decreased white blood cells which may make you more prone to infections
- if you notice an orange colouring of your urine, SALAZOPYRIN EN may cause this

Other medicines and SALAZOPYRIN EN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking other medicines on a regular basis, concomitant use of SALAZOPYRIN EN may cause undesirable interactions. SALAZOPYRIN EN sometimes affects the action of other medicines and sometimes SALAZOPYRIN EN is affected by other medicines.

Make sure your doctor knows if you are taking any of the following medicines:

- folate
- digoxin (used to treat heart conditions)
- azathioprine (used to treat conditions including rheumatoid arthritis, Crohn’s disease and to prevent kidney transplant rejection)
- oral coagulants (medicines used to support clotting and reduce the risk of bleeding)
- methotrexate (used to treat certain cancers, psoriasis and rheumatoid arthritis)
- phenytoin and paraldehyde (used to prevent seizures (fits))
- warfarin (used to thin the blood)

- probenecid and sulfinpyrazone (used to treat gout)
- spironolactone and furosemide (used to treat high blood pressure and heart failure)
- rifampicin (used to treat bacterial infections)
- iron
- local anaesthetics
- antibiotics

SALAZOPYRIN EN can influence the absorption of specific wavelengths of light within the body, which may result in complications during certain laboratory tests, particularly those assessing liver or muscle function, ammonia levels, thyroid hormone levels, or blood sugar levels. Prior to undergoing laboratory testing, it is imperative to inform the testing facility if you are currently taking SALAZOPYRIN EN. This precaution ensures appropriate adjustments or considerations can be made by the laboratory staff.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take SALAZOPYRIN EN if you are pregnant or breastfeeding your baby.

Driving and using machines

SALAZOPYRIN EN may affect your ability to drive and use machines.

It is not always possible to predict to what extent SALAZOPYRIN EN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SALAZOPYRIN EN affects them.

3. How to take SALAZOPYRIN EN

Do not share medicines prescribed for you with any other person.

Always take SALAZOPYRIN EN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

SALAZOPYRIN EN is available as a tablet to be taken preferably with meals. Take the tablet as prescribed by your doctor.

Your doctor will tell you how long your treatment with SALAZOPYRIN EN will last. Do not stop treatment early. If you have the impression that the effect of SALAZOPYRIN EN is too strong or too weak, tell your doctor or pharmacist.

If you take more SALAZOPYRIN EN tablets than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. If you have accidentally taken too many tablets, tell your doctor straight away. You may require medical attention.

If you forget to take SALAZOPYRIN EN tablets

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SALAZOPYRIN EN can have side effects.

Not all side effects reported for SALAZOPYRIN EN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SALAZOPYRIN EN, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased white blood cells and red blood cell abnormalities
- loss of appetite
- dizziness
- headache
- changes in taste
- ringing in the ears
- cough
- gastric distress (bloating and cramping)
- nausea (feeling sick)
- stomach pain
- itching
- skin rash accompanying disease or fever
- reddening of the skin
- itchy, red, swollen lumps
- pain in the joints
- kidney disorder (which causes protein loss in urine)
- urine may be orange coloured
- low sperm count
- fever

Less frequent side effects:

- swelling or inflammation of the large intestine
- inflammation of the salivary glands
- blood cell disorders
- underactive thyroid
- low blood sugar (experienced with high doses)
- depression
- inability to sleep
- hallucinations (seeing or hearing things that are not there)

- prickly, tingling feeling
- lack of muscle coordination
- inflammation of the peripheral nerves
- seizures (fits)
- multiple sclerosis (nerve disease affecting the brain, spinal cord and eyes)
- abnormal movement disorder
- yellow staining of soft contact lenses
- damage to the nerves in the eye
- short term short-sightedness
- swelling around the eyes
- feeling of falling
- bluish or purplish discolouration of the skin or mucous membranes
- inflammation of the blood vessels
- inflammation and thickening of the walls of the alveoli (the tiny air sacs in the lungs)
- difficulty breathing
- inflammation of the mouth and lips
- inflammation of the liver
- hair loss
- skin rash
- sensitivity to light
- red, itchy rash caused by direct contact with a substance or an allergic reaction to it
- peeling of the skin over large areas of the body
- severe, life-threatening skin conditions
- reddish, painful, tender lumps
- blood in the urine
- tiredness
- swelling of the face
- generalised hypersensitivity (allergic) reaction to SALAZOPYRIN EN including a condition resembling coughing, asthmatic attacks

- increased liver enzymes

Other side effects:

- aseptic meningitis (swelling of the protective membranes covering the brain and spinal cord in patients with rheumatoid disease)
- other blood disorders including low blood cell counts, lack of certain white blood cells, bone marrow problems, large red blood cells, and types of anaemia that affect the size and function of blood cells
- serum sickness (allergic reaction where you may experience fever, rash, inflammation and joint pain)
- changes in the sense of smell (anosmia)
- inflammation of the sac-like layers surrounding the heart (pericarditis)
- inflammation of the pancreas (pancreatitis)
- sudden onset of liver inflammation and damage
- systemic lupus erythematous (inflammatory disease affecting the tissues)
- disorder of the immune system (system which helps the body fight infections and other diseases)
- swelling in between the kidney tubules
- presence of crystals in the urine
- serious, life-threatening allergic reaction
- folate deficiency (folate also known as folic acid, is needed by the body to function normally)
- inflammation of the heart muscle (myocarditis)
- paleness (loss skin or mucous normal colour)
- progressive scarring of lung tissue (interstitial lung disease)
- sore throat
- diarrhoea
- vomiting
- worsening of inflammation of the digestive tract
- yellow discolouration of skin and body fluids

- liver failure
- sudden onset of liver inflammation and damage
- red or purple spots on the skin
- DRESS (drug rash with eosinophilia and systemic symptoms) - reaction of your body to SALAZOPYRIN EN whereby you may experience rash, fever, inflammation of the internal organs and blood disorders
- sudden swelling and redness of the skin with development of small white pus-filled spots (pustules) (pustuloderma)
- skin condition that usually appears as itchy, flat-topped bumps or lesions on the skin. These bumps can be reddish-purple in colour and may have fine white lines running over them (lichen planus)
- kidney stones

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SALAZOPYRIN EN.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store SALAZOPYRIN EN

- Store all medicines out of reach of children.
- Store at or below 30 °C. Protect from moisture.
- Do not use SALAZOPYRIN EN after the expiry date which is printed on the label.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SALAZOPYRIN EN contains

- The active substance is sulphasalazine. Each enteric coated tablet contains sulphasalazine 500 mg.
- The other ingredients are maize starch, magnesium stearate and colloidal silicon dioxide. The tablet coating contains cellulose acetate phthalate, propylene glycol, acetone and ethanol. The polish contains white beeswax, carnauba wax, self-emulsifying glycerol monostearate, polyethylene glycol 20 000, ethanol and talc.

What SALAZOPYRIN EN looks like and contents of the pack

SALAZOPYRIN EN 500 mg: Tablets are yellow-orange, elliptical, convex, film-coated tablets with ‘KPh’ on the one side and ‘102’ on the other.

Individual tablets of SALAZOPYRIN EN 500 mg packed in a white plastic bottle of 100 tablets.

Holder of Certificate of Registration

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