PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: [S3]

SALOFALK 500 mg, 1 000 mg, 1,5 g (gastro-resistant prolonged- release granules)

Mesalazine

Contains Sugar and sweetener

Read all of this leaflet carefully before you start taking SALOFALK granules

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SALOFALK granules 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 SALOFALK granules are and what they are used for

2. What you need to know before you take SALOFALK granules

3. How to take SALOFALK granules

4. Possible side effects

5. How to store SALOFALK granules

6. Contents of the pack and other information

1. What SALOFALK granules are and what they are used for

SALOFALK granules contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

SALOFALK granules are used for the treatment of acute episodes and prevention of further episodes (recurrence) of a chronic inflammatory disease of the large intestine (colon), known by doctors as ulcerative colitis.

2. What you need to know before you take SALOFALK granules Do not take SALOFALK granules:

- If you are allergic to mesalazine, salicylic acid, to salicylates such as aspirin or to any of the other ingredients of this medicine listed in **section 6**.
- If you have a serious liver or kidney disease
- If you are ≥ 20 weeks pregnant (see **Pregnancy, breastfeeding**)

Warning and precautions

Take special care with SALOFALK granules

Tell your doctor, pharmacist or health care provider if the following apply to you or the following complications occur due to SALOFALK granules treatment:

- If you have a history of problems with your lungs, particularly if you suffer from bronchial asthma (a chronic inflammatory disease of the airways that causes periodic attacks of coughing, wheezing, shortness of breath, and chest tightness)
- If you have a history of allergy to sulphasalazine, a substance related to mesalazine
- If you suffer with problems of your liver
- If you suffer with problems of your kidney

- If you have phenylketonuria (SALOFALK granules contains aspartame).

During treatment your doctor may want to keep you under close medical supervision, and you may need to have regular blood and urine tests.

Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

You may develop Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) which is severe cutaneous drug-induced eruption characterised by a virus like symptoms such as fever, facial swelling, enlarged lymph nodes and kidney or liver injury. If such signs or symptoms are present, discontinue SALOFALK granules and inform your doctor immediately.

Children and adolescents

There is only limited documentation for an effect in children (age 6-18 years).

Other medicines and SALOFALK granules

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

Please inform your doctor, pharmacist or health care provider if you are taking any of the following medicines, as you may require special precautions:

- Azathioprine, 6-mercaptopurine or thioguanine (medicines used to treat immune disorders)
- Certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood, e.g. warfarin)

- Lactulose (medicine used to treat constipation) or other preparations that can change the acidity of your stools.

Taking SALOFALK granules with food, drink and alcohol

SALOFALK 1,5 g can be taken with or without food.

Pregnancy, breastfeeding

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

You should only use SALOFALK granules during pregnancy if your doctor tells you to.

You should also only use SALOFALK granules during breastfeeding if your doctor tells you to, as this medicine may pass into breast milk.

Do not take SALOFALK granules around 20 weeks or later in pregnancy as it may cause kidney problems in your unborn baby, which may lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies lungs and muscles develop. Complications can occur with low levels of this fluid.

Driving and using machinery

SALOFALK granules have no or negligible influence on the ability to drive or use machines.

SALOFALK granules contain aspartame, sucrose and sodium

This medicine contains 3 mg aspartame per sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

3. How to take SALOFALK granules:

Do not share medicines prescribed for you with any other person.
Always take SALOFALK granules exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

SALOFALK granules are for oral use only.

SALOFALK granules should not be chewed. You should take the SALOFALK granules by placing the granules on the tongue and then swallowing them with plenty of liquid without chewing.

The usual dosage is:

SALOFALK 500 mg

Age and body weight	**Single dose**	**Total daily dose**
Adults, the elderly and children weighing more than 40 kg		

Treatment of acute episodes	1 to 6 sachets SALOFALK 500 mg granules	1 x 3-6 sachets or 3 x 1-2 sachets
Prevention of further episodes (for patients at increased risk for recurrence)	1 to 6 sachets SALOFALK 500 mg granules	3 x 1 sachet or 1 x 6 sachets
Children 6 years of age and older		
Treatment of acute episodes		30-50 mg mesalazine/kg body weight/day once daily or in divided doses
Prevention of further episodes		15-30 mg mesalazine/kg body weight/day in divided doses

SALOFALK 1000 mg

Age and body weight	**Single dose**	**Total daily dose**
Adults, the elderly and children weighing more than 40 kg		
Treatment of acute episodes	Up to 3 sachets SALOFALK 1 000mg granules	1 x 3 sachets or 3 x 1 sachets
Prevention of further episodes	3 sachets SALOFALK 1000mg granules	1 x 3 sachet

(for patients at increased risk for recurrence)		
Children 6 years of age and older		
Treatment of acute episodes		30 – 50 mg mesalazine/kg body weight/day once daily or in divided doses
Prevention of further episodes		15 – 30 mg mesalazine/kg body weight/day in divided doses

SALOFALK 1,5 g

Age and body weight	**Single dose**	**Total daily dose**
Adults, the elderly and children weighing more than 40 kg		
Treatment of acute episodes	Up to 2 sachets SALOFALK 1,5 g granules	1 x 1-2 sachets
Prevention of further episodes (for patients at increased risk for recurrence)	2 sachets SALOFALK 1,5 g granules	1 x 2 sachets

Adults and the elderly

Unless otherwise prescribed by your doctor, the normal dosage for the treatment of acute episodes of ulcerative colitis is 1-2 sachets of SALOFALK 1,5 g once daily, preferably in the morning (equivalent to 1,5 – 3 g mesalazine per day) depending on the nature and severity of your disease.

To prevent a relapse of ulcerative colitis

The normal dosage to prevent further episodes of ulcerative colitis is 1 sachet of SALOFALK 500 mg granules three times daily (equivalent to 1,5 g mesalazine per day).

If upon the decision of your doctor you are at increased risk for recurrence the dosage is 2 sachets of SALOFALK 1,5 g once daily, preferably in the morning (equivalent to 3 g mesalazine per day).

Use in children:

There is only limited documentation for an effect in children (age 6 – 18 years).

Children 6 years of age and older

Please ask your doctor about the precise dosage of SALOFALK granules for your child.

In acute episodes

To be determined individually, starting with 30 – 50 mg mesalazine per kg body weight per day that should be given once daily preferably in the morning or in divided doses. The maximum dose is 75 mg mesalazine per kg body weight per day. The total dose should not exceed the maximum adult dose.

It is generally recommended that half the adult dose should be given to children up to a body weight of 40 kg and the normal adult dose to those above 40 kg.

Due to their high content in active substance, SALOFALK 1,5 g are not suitable for children weighing less than 40 kg. Please use SALOFALK 500 mg or SALOFALK 1 000 mg instead.

Your doctor will decide how long you need to continue the treatment with this medicine. This will depend on the nature, severity and course of your condition. If you have the impression that the effect of SALOFALK granules is too strong or too weak, tell your doctor or pharmacist.

To obtain the maximum benefit from this medicine, you should use SALOFALK granules regularly and consistently both during the acute episode of inflammation and also as long-term treatment, as directed.

If you take more SALOFALK granules than you should:

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control centre.

If you use too much SALOFALK granules on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

If you forget to take SALOFALK granules

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to a regular schedule.

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

If you stop taking SALOFALK granules

Do not stop taking this product until you have talked to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

SALOFALK granules can cause side effects , although not everybody gets them.

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

If any of the following happen, stop taking SALOFALK granules and tell your doctor, pharmacist or other health care provider immediately or go to the causality department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SALOFAK. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Allergic skin rash
- Fever
- Breathing difficulties.

These are all serious side effects. You may need urgent medical attention.

If you experience a marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth, stop using these granules and contact your doctor immediately. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood (a condition called agranulocytosis), which may make you more prone to developing a serious infection. A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Abdominal pain
- Diarrhoea
- Dyspepsia
- Wind (flatulence)
- Nausea
- Vomiting
- Severe abdominal pain because of acute inflammation of the pancreas
- Changes in liver function parameters, changes in pancreatic enzymes
- Changes in the number of white blood cells.

Less frequent side effects:

- Dizziness
- Chest pain, breathlessness or swollen limbs because of an effect on your heart
- Jaundice or abdominal pain because of liver and bile flow disorders

- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- Joint pain
- Feeling weak or tired
- Fever, sore throat, or malaise because of blood count changes
- Skin rash or inflammation, allergic condition which causes joint pain, skin rashes and fever
- Severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel
- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Hair loss and the development of baldness
- Muscle pain
- Changes in kidney function, sometimes with swollen limbs or flank pain
- Reversible decrease in semen production.

Frequency unknown side effects:

Kidney stones and associated kidney pain (see **section 2**).

Severe cutaneous medicine-induced eruption characterised by a virus like symptoms (see **Warnings and Precautions**)

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, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SALOFALK granules. You can furthermore report side effects directly to the Cipla Medpro (Pty)Ltd , by an email at: drugsafetysa@cipla.com.

5. How to store SALOFALK granules

Store all medicines out of reach of children.

- Store in the original packaging at or below 30 °C.
- There are no special storage instructions for SALOFALK granules
- Do not use after the expiry date stated on the label carton
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewage systems (e.g. toilets).

6. Contents of the pack and other information

What SALOFALK granules contains

The active substance in SALOFALK 500 mg/ 1 000 mg/ 1,5 g is mesalazine and one sachet of SALOFALK 500 mg/ 1 000 mg/ 1,5 g granules contains 500 mg/ 1 000 mg/ 1,5 g mesalazine.

The other ingredients are aspartame, cellulose, microcrystalline, citric acid, anhydrous, Hypromellose, magnesium stearate, methacrylic acid-methyl methacrylate copolymer (1:1) [Eudragit L 100], methylcellulose, polyacrylate Dispersion 40 % (contains 2 % Nonoxynol

as emulsifier) [= Eudragit NE 40D], povidone, silica, colloidal anhydrous, simethicone, sodium carboxymethylcellulose, sorbic acid, talc, titanium dioxide, triethyl citrate, vanilla custard flavouring (containing sucrose).

What SALOFALK granules looks like and contents of the pack

What SALOFALK granules looks like

The granules are rounded, stick-formed or round particles, greyish white.

Contents of the pack

SALOFALK granules are packed into sachets consisting of a PET12/ ALU9/ PE50 foil in which the PE-layer is in direct contact with the medicine.

SALOFALK 1,5 g : 35, 70 or 100 sachets are packed in a printed cardboard carton.

SALOFALK 500 mg: 50 , 100 or 300 sachets are packed in a printed cardboard carton.

SALOFALK 1 000 mg: 50 , 100 or 150 sachets are packed in a printed cardboard carton.

Holder of Certificate of Registration

Cipla Medpro (Pty) Ltd.

Building 9, Parc du Cap

Mispel Street

Bellville, 7530

Company Contact

Phone: +27 21 943 4200

Customer Care: 080 222 6662

E-mail: info@cipla.com

This leaflet was last revised in

Not Applicable

Registration number

SALOFALK 1,5 g: 43/11.10/0086

SALOFALK 500 mg: 43/11.10/0195

SALOFALK 1 000 mg: 43/11.10/0196

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR code to be generated and included after approval