

SALOFALK SUPPOSITORIES

Mesalazine (250mg, 500mg)

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What Salofalk Suppositories are used for

Salofalk® 500mg Suppositories are used for the treatment of episodes of inflammatory disease at the large intestine, rectum and anal canal.

Salofalk® 250mg Suppositories are used for the treatment and prevent recurrence of episodes of inflammatory disease at the large intestine and rectum.

How Salofalk Suppositories work

Salofalk Suppositories are anti-inflammatory agent.

Before you use Salofalk Suppositories

- When you must not use it

Do not use Salofalk Suppositories

- If you are or have been told you are hypersensitive (allergic) to salicylic acid, salicylates such as Aspirin or any of the other ingredients of this medicine.
- If you have a serious liver or kidney disease.

- If you have gastric and duodenal ulcers.
- If you have abnormal tendency to spontaneous bleeding.

- Before you start to use it

Before you start using this medicine you should tell your doctor:

- If you have a history of problems with your lungs, particularly if you suffer from **asthma**.
- 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**.

- Taking other medicines

Please tell your doctor if you take or use any of the medicines mentioned below as the effects of these medicines may change (interactions):

- Anticoagulants used for blood thinning
- Glucocorticoids used as anti-inflammatory agent
- Sulphonyl ureas used to treat diabetic conditions
- Methotrexate used to treat immune disorders
- Probenecid/ sulphinpyrazone used to treat gout
- Spironolactone/ furosemide used to treat high blood pressure
- Rifampicin (antibiotic used to treat bacterial infections including tuberculosis)

Please tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. It may still be all right for you to use Salofalk Suppositories and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are

planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You should only use Salofalk Suppositories during pregnancy if your doctor tells you to.

You should also only use Salofalk Suppositories during breast-feeding if your doctor tells you to, as this medicine and its metabolites may pass into breast milk. If the infant develops diarrhoea, the breastfeeding should be discontinued.

Salofalk® 500mg Suppositories contains cetyl alcohol
Cetyl alcohol can cause local skin irritation (e.g. contact dermatitis).

How to use Salofalk Suppositories

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine may only be used rectally, so it has to be inserted through the anus. Do **NOT take by mouth**.

-How much to use

The recommended dose is:

Adults and elderly

For the treatment of acute symptoms of inflammation, insert **one** Salofalk® 500mg Suppositories **or two** Salofalk® 250mg Suppositories into the

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anus 3 times daily (equivalent to 1500 mg mesalazine daily).

In long-term treatment and to prevent recurrences, insert one

Salofalk® 250mg Suppositories into the anus 3 times daily (equivalent to 750 mg mesalazine daily).

Use in children

Salofalk Suppositories should not be used to treat infants and small children because of insufficient experience with this age group.

-When to use it

Use 3 times daily, in the morning, mid-day and in the evening.

To obtain the maximum benefit from this medicine, you should use Salofalk Suppositories regularly and consistently, as directed.

If you think your Salofalk Suppositories effect are too strong or too weak, talk to your doctor or pharmacist.

-How long to use it

Your doctor will decide how long you need to continue the treatment with this medicine. This will depend on your condition.

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

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until the time to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

-Things you must do

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Should Salofalk® 500mg Suppositories cause acute intolerance reactions such as abdominal cramps, acute abdominal pain, fever, severe headache and rash, therapy should be discontinued immediately.

-Things you must not do

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

-Things to be careful of

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

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

The following are possible side effects of using this medicine:

- Abdominal discomfort, diarrhea, flatulence, nausea, vomiting
- Headache, dizziness
- Skin rash
- Fever
- Breathing difficulty

- Liver inflammation
- Changes in blood count and liver function test
- Joint and muscle pain
- Hair loss and the development of baldness
- Numbness and tingling in the hands and feet
- Reversible low sperm concentration in semen production

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Salofalk Suppositories

-Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the strip for the suppositories and on the carton. The expiry date refers to the last day of that month.

Do not store above 25 °C (Salofalk® 250mg Suppositories)

Do not store above 30 °C (Salofalk® 500mg Suppositories)

Store in the original container in order to protect contents from light.

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-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Manufacturer

Vifor AG,
Zweigniederlassung,
Medichemie Ettingen,
Brühlstrasse 50
4107 Ettingen
Switzerland

Product Description

-What it looks like

Salofalk Suppositories are white to cream-coloured, torpedo-shaped suppositories.

For:

Dr. Falk Pharma GmbH
Leinenweberstr.5
79108 Freiburg
Germany

Salofalk Suppositories are available in packs of 10 and 30 suppositories.

Not all package sizes may be marketed.

Product Registration Holder

DCH Auriga (Malaysia) Sdn Bhd (719-V)
(f.k.a. LF Asia (Malaysia) Sdn Bhd)
Lot 6, Persiaran Perusahaan, Seksyen 23,
40300 Shah Alam,
Selangor Darul Ehsan

-Ingredients

-Active ingredient:

The active substance in Salofalk Suppositories is mesalazine. One Salofalk[®] 250mg Suppositories contains 250mg mesalazine whereas one Salofalk[®] 500mg Suppositories contains 500mg mesalazine.

Date of Revision

12/07/ 2018

Serial Number

NPRA(R4/1)110718/00194

-Inactive ingredient:

The other ingredient in Salofalk[®] 250mg Suppositories is hard fat.
The other ingredients in Salofalk[®] 500mg Suppositories are hard fat, docusate sodium and cetyl alcohol

-MAL Number:

Salofalk[®] 250mg Suppositories:
MAL19912932ACZ

Salofalk[®] 500mg Suppositories:
MAL19972120ACZ