

SALOFALK[®] TABLETS

MESALAZINE

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start to take your medicine. It contains important information about your tablets. If you have any questions or are not sure about anything ask your doctor or pharmacist (chemist).

What your Tablets contain

Each tablet contains:

The active ingredient – mesalazine 250mg.

Other ingredients - sodium carbonate, glycine, povidone, microcrystalline cellulose (E460), colloidal anhydrous silica, calcium stearate, hydroxypropylmethyl cellulose (E464), methacrylic acid copolymer, talc, titanium dioxide (E171), iron oxide (E172), polyethylene glycol and polymethacrylate.

This product contains 48mg sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

Salofalk[®] is supplied in boxes containing 100 yellow tablets in blister packs.

What your Tablets do

Salofalk[®] tablets contain a substance called mesalazine. This is one of a group of medicines called amino-salicylates. Salofalk[®] is effective in treating a disease of the lower bowel known as ulcerative colitis.

Product Licence Holder:

Interfalk UK Ltd, Thames House, Wellington Street, London SE18 6NZ.

Manufactured by:

Dr. Falk Pharma GmbH, D-79041, Freiburg, Germany.

Distributed by:

Dr Falk Pharma UK Ltd, Unit K, Bourne End Business Park, Cores End Road, Bourne End, Bucks SL8 5AS, UK.

Before taking Salofalk[®] Tablets

- The medicine should not be taken by babies or infants.
- If you are pregnant, think you may be pregnant or are trying to become pregnant or breastfeeding you should tell your doctor.

*If the answer to any of the following questions is **yes**, tell your doctor or pharmacist.*

- Have you been told or do you think you may be sensitive to mesalazine or any other ingredient in Salofalk[®] tablets?
- Do you suffer from kidney or liver disease?
- Do you have or have you ever had a stomach or duodenal ulcer?
- Do you suffer from diabetes?
- Do you tend to bleed easily or have you ever been told that there is a problem with the clotting of your blood?
- Are you taking any medicines for thrombosis or to thin your blood?
- Are you taking any anti-inflammatory agents or drugs for pain relief?
- Are you taking any medicines for the treatment of gout, heart problems, leukaemia, tuberculosis or any other medicines which your doctor does not know about?

Taking Salofalk® Tablets

It is important to take Salofalk® as directed by your doctor. The usual dose is: Adults (including the elderly): for short term treatment, six tablets daily in three divided doses. For long term treatment, three to six tablets in divided doses.

- The tablets should not be chewed but swallowed whole with a glass of water.
- If you accidentally take too many tablets tell your doctor immediately or go to your nearest hospital casualty department.
- If you forget to take your tablets, take a dose as soon as you remember and then continue with the next dose as instructed on the label.
- If you go into hospital or visit a dentist or another doctor tell them you are taking this medicine.

After taking Salofalk® Tablets

Like all medicines, Salofalk® may occasionally cause unwanted effects in some people. Normally these effects are mild and rare but if you experience any of the following effects stop taking the tablets and tell your doctor as soon as possible.

- Changes in blood composition.
- Unexplained bleeding, bruising, fever or sore throat.
- Liver problems, which may result in yellowing of skin and eyes.
- Skin rash, inflammation, blistering and peeling skin (sometimes severe).
- Chest tightness or shortage of breath.
- Numbness or tingling in the hands or feet.
- Kidney function disturbances, which may result in swelling of ankles, feet or lower leg.
- If you become dehydrated (lose too much water) which can occur with severe or prolonged vomiting and/or diarrhoea, high fever or excess sweating, contact your doctor or pharmacist for advice. Adequate fluid replacement is important in preventing kidney problems.

If you experience any other undesirable effects then tell your doctor or pharmacist, particularly if they are severe or persistent.

Storing Salofalk® Tablets

- No special storage precautions are required for Salofalk® tablets but keep them in a place where children cannot reach them, your medicine could harm them.
- Check the expiry date on the side of the box or blister pack and do not use the tablets if this date has been passed.
- If your doctor decides to stop treatment, return any left over tablets to the pharmacist. Only keep them if the doctor tells you to.
- If the tablets look to be deteriorating in any way, do not take them, and return them to the pharmacist.

This leaflet provides a summary of the information available on your medicine. This information applies only to Salofalk® tablets. If you have any questions or are not sure of anything, ask your doctor or pharmacist who have access to additional information.

REMEMBER: This medicine is for you. Never give it to anyone else. It may not be suitable for them even if their symptoms are the same as yours.

YOU MAY WANT TO READ THIS LEAFLET AGAIN.
PLEASE DO NOT THROW IT AWAY UNTIL YOU HAVE FINISHED YOUR MEDICINE.

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