

Instructions for use - please read carefully.

Salofalk[®] enemas

Active substance: Mesalazine

Composition:

Each Salofalk enema with 60 g suspension contains 4.0 g Mesalazine (5-aminosalicylic acid).

Indications:

Acute attack of ulcerative colitis.

Contraindications:

Severe hepatic and renal disease; active peptic ulcer; blood clotting abnormalities. Salofalk enemas should not be used in babies and infants. Salofalk should not be used in the case of pathological propensity to bleeding. There is to date insufficient experience on the use in lactation.

Side effects:

Salofalk may cause hypersensitivity reactions, such as allergic exanthemata, drug fever, bronchospasm, and a lupus erythematosus-like syndrome. These are unrelated to dose. Increased methaemoglobin levels may occur.

Drug interactions:

The hypoglycaemic action of the sulfonylureas can be intensified, as can gastrointestinal haemorrhage caused by coumarins. The toxicity of methotrexate can be increased. The uricosuric action of probenecide and sulfinpyrazone can be decreased, as can the diuretic action of furosemide and the action of spironolactone. The antituberculosis action of rifampicin can also be diminished.

Dosage, administration and duration of therapy:

Unless prescribed otherwise, the contents of one enema vial (60 g suspension) are given once per day rectally before retiring. The best results are obtained if gut lavage is carried out prior to the Salofalk enema.

Shake well before use to homogenize the suspension.

Remove the protective cap, and hold the vial vertically to avoid spilling the contents. Lie on your left side, stretch out your left leg and pull your right leg in at an angle to keep your balance. Insert the applicator, which is coated with a lubricative for easy insertion into the rectum, holding the vial pointed towards your navel.

Holding the vial tightly, bend yourself slightly so that the applicator is pointing towards your back. Now press the plastic vial slowly to avoid triggering off a passage of stool. After use, remove the empty vial from the rectum.

Keep lying in the same position for 30 minutes to enable the enema to spread evenly into the intestines. The best effect is obtained by letting the enema work overnight.

The duration of therapy is determined by the physician.

In general, the acute attack disappears after 8–12 weeks. Do not use Salofalk enemas after the acute attack is over.

Note:

Salofalk enemas must not be used after the expiry date printed on the package.

Storage:

Do not store above 25° C (77° F)!

Availability:

Pack containing 7 enemas.



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