

**SALOFALK® ENEMA****Treatment of acute attack of mild to moderate ulcerative colitis or maintenance of remission**

- ▶ BY RECTUM
- ▶ Child 12–17 years: 2 g once daily, dose to be administered at bedtime

**SALOFALK® GRANULES****Treatment of mild to moderate ulcerative colitis, acute attack**

- ▶ BY MOUTH
- ▶ Child 5–17 years (body-weight up to 40 kg): 30–50 mg/kg once daily, dose preferably given in the morning, alternatively 10–20 mg/kg 3 times a day
- ▶ Child 5–17 years (body-weight 40 kg and above): 1.5–3 g once daily, dose preferably given in the morning, alternatively 0.5–1 g 3 times a day

**Maintenance of remission of ulcerative colitis**

- ▶ BY MOUTH
- ▶ Child 5–17 years (body-weight up to 40 kg): 7.5–15 mg/kg twice daily, total daily dose may alternatively be given in 3 divided doses
- ▶ Child 5–17 years (body-weight 40 kg and above): 500 mg 3 times a day

**SALOFALK® RECTAL FOAM****Treatment of mild ulcerative colitis affecting sigmoid colon and rectum**

- ▶ BY RECTUM
- ▶ Child 12–17 years: 2 g once daily, dose to be administered into the rectum at bedtime, alternatively 2 g daily in 2 divided doses

**SALOFALK® SUPPOSITORIES****Treatment of acute attack of mild to moderate ulcerative colitis affecting the rectum, sigmoid colon and descending colon**

- ▶ BY RECTUM
- ▶ Child 12–17 years: 0.5–1 g 2–3 times a day, adjusted according to response, dose to be given using 500 mg suppositories

**SALOFALK® TABLETS****Treatment of mild to moderate ulcerative colitis, acute attack**

- ▶ BY MOUTH
- ▶ Child 5–17 years (body-weight up to 40 kg): 10–20 mg/kg 3 times a day
- ▶ Child 5–17 years (body-weight 40 kg and above): 0.5–1 g 3 times a day

**Maintenance of remission of ulcerative colitis**

- ▶ BY MOUTH
- ▶ Child 5–17 years (body-weight up to 40 kg): 7.5–15 mg/kg twice daily, total daily dose may alternatively be given in 3 divided doses
- ▶ Child 5–17 years (body-weight 40 kg and above): 500 mg 3 times a day

**● UNLICENSED USE**

- ▶ With oral use *Asacol*® (all preparations) not licensed for use in children under 18 years. *Pentasa*® tablets not licensed for use in children under 15 years. *Pentasa*® granules and *Salofalk*® tablets and granules not licensed for use in children under 6 years.
- ▶ With rectal use *Asacol*® (all preparations) and *Salofalk*® enema not licensed for use in children under 18 years. *Salofalk*® suppositories and *Pentasa*® suppositories not licensed for use in children under 15 years. *Salofalk*® rectal foam no dose recommendations for children (age range not specified by manufacturer).

**● CONTRA-INDICATIONS** Blood clotting abnormalities**● CAUTIONS** Pulmonary disease**● INTERACTIONS** → Appendix 1: mesalazine**● SIDE-EFFECTS****GENERAL SIDE-EFFECTS**

- ▶ Rare or very rare Cholestasis exacerbated · drug fever · flatulence · nephritis

**SPECIFIC SIDE-EFFECTS**

- ▶ Rare or very rare
  - ▶ With rectal use Constipation
- PREGNANCY Negligible quantities cross placenta.
- BREAST FEEDING Diarrhoea reported in breast-fed infants, but negligible amounts of mesalazine detected in breast milk.
  - Monitoring Monitor breast-fed infant for diarrhoea.

- HEPATIC IMPAIRMENT Manufacturer advises caution in mild to moderate impairment; avoid in severe impairment.

- RENAL IMPAIRMENT Use with caution. Avoid if estimated glomerular filtration rate less than 20 mL/minute/1.73 m<sup>2</sup>.

**● DIRECTIONS FOR ADMINISTRATION**

**PENTASA® TABLETS** Tablets may be halved, quartered, or dispersed in water, but should not be chewed.

**PENTASA® GRANULES** Granules should be placed on tongue and washed down with water or orange juice without chewing.

Contents of one sachet should be weighed and divided immediately before use; discard any remaining granules.

**SALOFALK® GRANULES** Granules should be placed on tongue and washed down with water without chewing.

- PRESCRIBING AND DISPENSING INFORMATION There is no evidence to show that any one oral preparation of mesalazine is more effective than another; however, the delivery characteristics of oral mesalazine preparations may vary.

Flavours of granule formulations of *Salofalk*® may include vanilla.

- PATIENT AND CARER ADVICE If it is necessary to switch a patient to a different brand of mesalazine, the patient should be advised to report any changes in symptoms. Some products may require special administration advice; patients and carers should be informed.

Medicines for Children leaflet: Mesalazine (oral) for inflammatory bowel disease [www.medicinesforchildren.org.uk/mesalazine-oral-inflammatory-bowel-disease](http://www.medicinesforchildren.org.uk/mesalazine-oral-inflammatory-bowel-disease)

Medicines for Children leaflet: Mesalazine foam enema for inflammatory bowel disease [www.medicinesforchildren.org.uk/mesalazine-foam-enema-inflammatory-bowel-disease](http://www.medicinesforchildren.org.uk/mesalazine-foam-enema-inflammatory-bowel-disease)

Medicines for Children leaflet: Mesalazine liquid enema for inflammatory bowel disease [www.medicinesforchildren.org.uk/mesalazine-liquid-enema-inflammatory-bowel-disease](http://www.medicinesforchildren.org.uk/mesalazine-liquid-enema-inflammatory-bowel-disease)

Medicines for Children leaflet: Mesalazine suppositories for inflammatory bowel disease [www.medicinesforchildren.org.uk/mesalazine-suppositories-inflammatory-bowel-disease](http://www.medicinesforchildren.org.uk/mesalazine-suppositories-inflammatory-bowel-disease)

- MEDICINAL FORMS There can be variation in the licensing of different medicines containing the same drug.

**Modified-release tablet**

CAUTIONARY AND ADVISORY LABELS 21 (does not apply to Pentasa® tablets), 25 (does not apply to Pentasa® tablets)

- ▶ **Pentasa** (Ferring Pharmaceuticals Ltd)

**Mesalazine 500 mg** Pentasa 500mg modified-release tablets | 100 tablet [PoM] £30.74 DT = £30.74

**Mesalazine 1 gram** Pentasa 1g modified-release tablets | 60 tablet [PoM] £36.89 DT = £36.89

**Foam**

EXCIPIENTS: May contain Cetostearyl alcohol (including cetyl and stearyl alcohol), disodium edetate, hydroxybenzoates (parabens), polysorbates, propylene glycol, sodium metabisulfite

- ▶ **Salofalk** (Dr. Falk Pharma UK Ltd)

**Mesalazine 1 gram per 1 application** Salofalk 1g/application foam enema | 14 dose [PoM] £30.17 DT = £30.17