

Prescribing Information: Pentasa® all formulations

Please consult the full Summary of Product Characteristics before prescribing.

Name of Product(s): Pentasa® Sachet prolonged release granules 1g, 2g and 4g; Pentasa® Slow Release Tablets 500mg and 1g; Pentasa® Mesalazine Enema; Pentasa® Suppositories 1g. **Composition:** *Sachets:* contain 1g, 2g or 4g mesalazine. *Tablets:* contain 500mg or 1g mesalazine. *Enema:* contains 1g mesalazine in 100ml of aqueous suspension. *Suppositories:* contain 1g mesalazine. **Indication:** *Sachets and Tablets:* Mild to moderate ulcerative colitis. *Enema:* ulcerative colitis affecting the distal colon and rectum. *Suppositories:* ulcerative proctitis. **Dosage:** *Sachets and Tablets:* Adults: Active disease: up to 4g once daily or in 2–4 divided doses. Maintenance treatment: 2g once daily. *Sachets:* Children over 6 years old: Active disease: individual dosing, starting with 30-50 mg/kg/day in divided doses (total dose should not exceed 4g/day). Maintenance treatment: individual dosing, starting with 15-30 mg/kg/day in divided doses (total dose should not exceed 2g/day). *Enema:* Adults: one enema at bedtime. *Suppositories:* Adults: 1 suppository daily. **Contraindications:** Hypersensitivity to mesalazine, or salicylates, or any other excipients of the product; severe liver and/or renal impairment. *Tablets and Suppositories:* children under 15 years of age. **Special Warnings and Precautions:** Caution is recommended in patients allergic to sulphasalazine or with impaired liver or renal function. Not recommended for use in patients with renal impairment. Serious blood dyscrasias and cardiac hypersensitivity reactions have been reported rarely with mesalazine; treatment should be stopped if there is suspicion or evidence of these reactions. Do not use during pregnancy and lactation except when the potential benefits outweigh the possible risk. *Sachets:* Caution is recommended in patients with haemorrhagic diathesis or active peptic ulcer. Patients with pulmonary disease, in particular asthma, should be very carefully monitored during a course of treatment. Concurrent use of other known nephrotoxic agents may increase the risk of renal reactions. *Sachets and Tablets:* Monitoring of liver function parameters, urinary status and differential blood counts are recommended prior to and during treatment. *Tablets, Enema and Suppositories:* If a patient develops dehydration while on treatment with mesalazine, normal electrolyte levels and fluid balance should be restored as soon as possible. **Side effects:** For the full list of side effects please consult the Summaries of Product Characteristics. Common: headache, nausea, vomiting, diarrhoea, abdominal pain, rash. Rare: dizziness, myocarditis, pericarditis, pancreatitis, increased amylase, flatulence. Very rare: eosinophilia, altered blood counts, hypersensitivity reactions such as allergic exanthema, pancolitis, peripheral neuropathy, benign intracranial hypertension in adolescents, allergic lung reactions, increased liver enzymes and bilirubin, hepatotoxicity, (reversible) alopecia, Quincke's oedema, myalgia, arthralgia, single cases of lupus erythematosus-like reactions, renal function impairment, interstitial nephritis, nephrotic syndrome, renal insufficiency, urine discolouration, (reversible) oligospermia, drug fever. *Enema and Suppositories:* pruritus, rectal discomfort, urge. **Nature and Contents of Container:** *Sachets:* Cartons contain 50 x 1g sachets, 60 x 2g sachets or 30 x 4g sachets. *Tablets:* Cartons contain 100 x 500mg and 60 x 1g tablets in blister strips. *Enema:* Cartons contain 7 x 100ml enemas. *Suppositories:* Cartons contain 28 x 1g suppositories in blister strips. **Marketing Authorisation Number:** *Sachet 1g:* 03194/0075. *Sachet 2g:* 03194/0102. *Sachet 4g:* PL 03194/0117. *Tablets 500mg:* 03194/0044. *Tablets 1g:* 3194/0108. *Enema:* 03194/0027. *Suppositories:* 03194/0045. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, United Kingdom. **Legal Category:** POM. **Basic NHS Price:** £30.74 for 50 x 1g sachets. £73.78 for 60 x 2g sachets. £73.78 for 30 x 4g sachets. £30.74 for 100 x 500mg Tablets. £36.89 for 60 x 1g Tablets. £17.73 for 7 x enemas. £40.01 for 28 x 1g suppositories. **Date of Preparation of Prescribing Information:** March 2015. Pentasa is a registered trademark. PA/439/2011/UK(2)

Adverse events should be reported. Reporting forms and information can be found at
www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Ferring Pharmaceuticals Ltd.
Tel: 0844 931 0050. Email: medical@ferring.com