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 1g; 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 for sachets (2–3 divided doses for tablets). Maintenance treatment: 2g once daily. *Sachets and 500mg tablet:* 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:*** patients with known hypersensitivity to salicylates or any of the excipients and patients with severe liver and/or renal impairment. ***Special Warnings and Precautions:*** Blood tests (differential blood count: liver function parameters such as ALT or AST; serum creatinine) and urinary status should be determined prior to and during treatment, at the discretion of the treating physician. Caution is recommended in patients with impaired hepatic function. PENTASA should not be used in patients with impaired renal function. Mesalazine-induced renal toxicity should be considered, if renal function deteriorates during treatment. Patients with pulmonary disease, in particular asthma, should be very carefully monitored during a course of treatment with PENTASA. Patients with a history of adverse drug reactions to preparations containing sulphasalazine (risk of allergy to salicylates), should be kept under close medical surveillance. Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment. Should PENTASA cause acute intolerance reactions such as abdominal cramps, acute abdominal pain, fever and severe headache and/or the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other signs of hypersensitivity the treatment should be discontinued immediately. Mesalazine-induced cardiac hypersensitivity reactions (myo- and pericarditis) have been reported rarely. Treatment should be discontinued on suspicion or evidence of these reactions. In patients who are concomitantly treated with azathioprine, or 6-mercaptopurine, or thioguanine, a possible increase in the myelosuppressive effects of azathioprine, or 6-mercaptopurine, or thioguanine should be taken into account. There may be a decrease in the anticoagulant effect of warfarin. Do not use during pregnancy and lactation except when the potential benefits outweigh the possible risk. *Sachets:* Caution is recommended in patients with active peptic ulcer disease. The concurrent use of other known nephrotoxic agents, such as NSAID's and azathioprine, may increase the risk of other renal reactions. *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. *PENTASA 1g 2g 4g sachets:* Common: Headache, Diarrhoea, Abdominal pain, Nausea, Vomiting, Flatulence. Rare: Acute pancreatitis. Very rare: Benign intracranial hypertension, Pericardial effusion, Quincke's oedema, Dermatitis allergic, Hypersensitivity reaction including anaphylactic reaction, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). *Pentasa all formulations:* Rare: Dizziness, Myocarditis, Pericarditis, Photosensitivity. Very rare: Altered blood counts, Hypersensitivity reaction such as Allergic exanthema, Drug fever, Lupus erythematosus syndrome, Pancolitis, Peripheral neuropathy, Allergic and Fibrotic lung reactions, Changes in liver function parameters, Hepatitis and Cholestatic hepatitis, (Reversible) Alopecia, Renal function impairment interstitial, Nephritis (incl. acute and chronic), Renal insufficiency, Reversible oligospermia. *PENTASA 1g 2g 4g sachets, 1g enema and 1g suppository:* Common: Rash. Rare: Increased amylase. Very rare: Cirrhosis, Hepatic failure, Erythema multiforme, Nephrotic syndrome, Urine discolouration. *PENTASA 500mg and 1g tablets, 1g enema and 1g suppository:* Rare: Abdominal pain, Diarrhoea, Flatulence, Nausea, Vomiting, Headache. Very Rare: Acute Pancreatitis. *PENTASA 1g enema and 1g suppository:* very rare SJS. ***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:** July 2021. Pentasa® is a registered trademark

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: 0800 111 4126.
Email: medical.uk@ferring.com

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