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 and administration:*** *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 mesalazine, salicylates or any of the excipients and patients with severe liver and/or renal impairment. ***Special Warnings and Precautions:*** Caution is recommended when treating patients allergic to sulphasalazine (risk of allergy to salicylates). Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment. In case of acute symptoms of intolerance, i.e. abdominal cramps, 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. Caution is recommended in patients with impaired liver function. Liver function parameters like ALT or AST should be assessed prior to and during treatment, at the discretion of the treating physician. The drug is not recommended for use in patients with impaired renal function and in patients with haemorrhagic diathesis. The renal function should be regularly monitored (e.g. serum creatinine), especially during the initial phase of treatment. Urinary status (dip sticks) should be determined prior to and during treatment at the discretion of the treating physician. Mesalazine-induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. The concurrent use of other known nephrotoxic agents, such as NSAIDs and azathioprine, may increase the risk of renal reactions. Caution is recommended in patients with active peptic ulcer. Patients with pulmonary disease, in particular asthma, should be very carefully monitored during a course of treatment. Mesalazine-induced cardiac hypersensitivity reactions (myo- and pericarditis) have been reported rarely. Serious blood dyscrasias have been reported very rarely with mesalazine. Blood tests for differential blood counts is recommended prior to and during treatment, at the discretion of the treating physician. Treatment should be discontinued on suspicion or evidence of these adverse reactions. Cases of nephrolithiasis have been reported with the use of mesalazine including stones with a 100% mesalazine content. It is recommended to ensure adequate fluid intake during treatment. As a guideline, follow-up tests are recommended 14 days after commencement of treatment, then a further two to three tests at intervals of 4 weeks. If the findings are normal, follow-up tests should be carried out every three months. If additional symptoms occur, these tests should be performed immediately. Combination therapy with PENTASA and azathioprine, or 6-mercaptopurine, or thioguanin, have shown a higher frequency of myelosuppressive effects and an interaction cannot be ruled out, however the mechanism behind the interaction is not established. Regular monitoring of white blood cells is recommended and the dosage regimen of thiopurine should be adjusted accordingly. There may be a decrease in the anticoagulant effect of warfarin. PENTASA should not be used during pregnancy and lactation except when the potential benefits of the treatment outweigh the possible hazards. The underlying condition itself (Inflammatory bowel disease (IBD)) may increase risks for adverse pregnancy outcome. Mesalazine is known to cross the placental barrier and its concentration in umbilical cord plasma is lower than the concentration in maternal plasma. The metabolite acetyl-mesalazine is found at similar concentrations in umbilical cord and maternal plasma. Limited published human data on mesalazine show no increase in the overall rate of congenital malformations. Some data show an increased rate of preterm birth, stillbirth, and low birth weight; however, these adverse pregnancy outcomes are also associated with active inflammatory bowel disease. Blood disorders (leucopenia, thrombocytopenia, anaemia) have been reported in new-borns of mothers being treated with PENTASA. In one single case after long-term use of a high dose of mesalazine (2-4 g, orally) during pregnancy, renal failure in a neonate was reported. Mesalazine is excreted in breast milk. The mesalazine concentration in breast milk is lower than in maternal blood, whereas the metabolite, -acetylmesalazine- appears in similar or increased concentrations. No controlled studies with PENTASA during breastfeeding have been carried out. Hypersensitivity reactions like diarrhoea cannot be excluded. If the infant develops diarrhoea, breastfeeding should be discontinued. Animal data on Mesalazine show no effect on male and female fertility. PENTASA has no or negligible influence on the ability to drive and/or use machines. ***Side effects***: For the full list of side effects please consult the Summaries of Product Characteristics. *Pentasa all formulations*: Common: Headache, Diarrhoea, Abdominal pain, Nausea, Vomiting, Flatulence and rash. Rare: Dizziness, Myocarditis, Pericarditis, Acute pancreatitis, Increased amylase (blood and/or urine), Photosensitivity, Very rare: Altered blood counts, Hypersensitivity reaction incl. anaphylactic reaction, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Peripheral neuropathy, Allergic alveolitis, Allergic and Fibrotic lung reactions, Pancolitis, Increased liver enzymes, cholestasis parameters and bilirubin, hepatotoxicity, (Reversible) Alopecia, dermatitis allergic, erythema multiforme, Myalgia, arthralgia, lupus erythematosus-like syndrome, Renal function impairment, nephrotic syndrome, renal insufficiency, urine discolouration, (Reversible) Oligospermia, Drug fever. *PENTASA 1g 2g 4g sachets:* Very rare: Benign intracranial hypertension, Pericardial effusion, Quincke's oedema. *PENTASA 1g enema, 1g suppositories:* Following rectal administration local reactions such as pruritus, rectal discomfort and urge may occur. ***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:** October 2022. Pentasa® is a registered trademark. UK-PA-2200033

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@ferring.com