.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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Mesren (Mesalazine) MR 400 mg tablets Abbreviated Prescribing Information

Presentation: Each tablet contains mesalazine 400 mg modified-release. **Indications:** Ulcerative Colitis: mild to moderate acute exacerbations and maintenance of remission. Crohn's ileo-colitis: maintenance of remission. **Dosage and administration:** *Adults*: Acute disease – Six tablets daily in divided doses with concomitant corticosteroid where indicated. Maintenance therapy – Three to six tablets daily in divided doses. *Elderly:* No dosage adjustment. *Renal impairment:* Use with extreme caution. *Children:* There is limited documentation for an effect in children aged 6-18 years and the dosage is to be determined individually, active disease – starting with 30-50 mg/kg/day in divided doses. Maximum dose is 4g/day. Maintenance treatment – starting with 15-30 mg/kg/day in divided doses. The total dose should not exceed 2 g/day. Swallow whole with water. Do not chew, crush or break. **Contraindications:** Patients with a history of allergy to salicylates, or hypersensitivity to any ingredient. Severe renal impairment (GFR less than 20 ml/min). Severe hepatic impairment. Gastric or duodenal ulcer, haemorrhagic tendency. **Precautions and warnings:** Monitor renal function prior to treatment, every three months for the first year, then six monthly for next four years and annually thereafter. Discontinue mesalazine if renal function deteriorates. Avoid tablets in mild to moderate renal impairment, if necessary, use with extreme caution. If dehydration develops, normal electrolyte levels and fluid balance should be restored as soon as possible. In lung function impairment, especially asthma, closely monitor patients. In patients with a history of sensitivity to sulphasalazine, only initiate therapy under close medical supervision. Stop immediately if acute symptoms of intolerance occur. Very rarely serious blood dyscrasia has been reported. Haematological investigations including a complete blood count should be performed prior to initiation and whilst on therapy according to physician's judgement. If results are normal, tests are recommended quarterly. If signs of additional illness appear, further control tests are necessary. Stop treatment immediately if there is suspicion or evidence of blood dyscrasia and patients should seek immediate medical advice. Contains lactose monohydrate. **Interactions:** Use with nephrotoxic agents may increase the risk of renal reactions. Mesalazine decreases the absorption of digoxin. Mesalazine can increase the immunosuppressive effects of azathioprine and 6-mercaptopurine. A blood count, especially leukocyte cell count should be monitored repeatedly, especially at initiation of combination therapy. Mesalazine may reduce the uricosuric activity of probenecid and sulfinpyrazone, the diuretic effect of furosemide and the activity of spironolactone. Gastrointestinal side-effects of glucocorticoids can be increased. **Pregnancy and lactation:** Assess benefit/risk. If suckling neonate develops diarrhoea, discontinue breast-feeding. **Effects on ability to drive and use machines:** Mesalazine has no, or negligible, influence on ability to drive and use machines. **Adverse reactions:** *Serious:* Blood dyscrasia, thrombocytopenia, leucopenia, neutropenia, pancytopenia, anaemia, aplastic anaemia, agranulocytosis and bone marrow depression. Myocarditis. Allergic lung reactions, bronchospasm, eosinophilicpneumonia. Pancreatitis and hepatitis. Bulbous skin reaction and Stevens Johnson syndrome. Lupus-erythematosus-like syndrome with pericarditis. Renal failure, which may be reversible on withdrawal, interstitial nephritis and nephrotic syndrome. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2.5 mmol/L). Most adult deaths occur when concentrations exceed 700 mg/L (5.1 mmol/L). Give activated charcoal if adult presents within one hour of ingestion of more than 250 mg/kg. Urinary alkalinisation by administration of 1.26% sodium bicarbonate to increase elimination. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Haemodialysis should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under 10 years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage. **Price:** Mesren MR 400 mg tablets, 90 tablets £19.50; 120 tablets £26.00. **Legal category:** POM. **Marketing Authorisation Numbers:** Mesren MR 400 mg tablets PL 00289/1644. **Marketing Authorisation Holder:** Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG

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