# MEZAVANT XL 1200mg gastro-resistant, Prolonged Release Tablets
## ABBREVIATED PRESCRIBING INFORMATION

Please refer to full package insert before prescribing (7 July 2021/ EU SmPC/ CCDS v22, 23)

**Active Ingredient:** Mesalazine 1200mg.

**I:** For the induction of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis. For maintenance of remission.

**A:** For adults, including the elderly (>65 years). To be administered with food. For induction of remission: 2.4 to 4.8g should be taken once daily. For maintenance of remission: 2.4g should be taken once daily.

**CI:** History of hypersensitivity to salicylates (including mesalazine) or any of the excipients of Mezavant XL. Severe renal impairment (GFR <30mL/min/1.73m2) and/or severe hepatic impairment.

**WP:** Mezavant XL should be used with caution in patients with confirmed mild to moderate renal impairment. All patients have an evaluation of renal function prior to initiation of therapy and at least twice a year, while on treatment. Patients with chronic lung function impairment, especially asthma, are at risk of hypersensitivity reactions and should be closely monitored. If the patient develops unexplained bleeding, bruising, purpura, anaemia, fever or sore throat, haematological investigations should be performed. If there is suspicion of blood dyscrasia, treatment should be terminated. Caution should be used in prescribing this medication to patients with conditions predisposing to the development of myo- or pericarditis. Severe cutaneous adverse reactions (SCARs), such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment. If acute intolerance syndrome is suspected, prompt withdrawal is required and products containing mesalazine must not be reintroduced. Caution is recommended if Mezavant XL is administered to patients with hepatic impairment. Caution should be exercised when treating patients allergic to sulphasalazine due to the potential risk of cross sensitivity reactions between sulphasalazine and mesalazine. Organic or functional obstruction in the upper gastrointestinal tract may delay onset of action of the product. Cases of nephrolithiasis have been reported with the use of mesalazine, it is recommended to ensure adequate fluid intake during treatment. This medicine contains less than 1 mmol sodium (23 mg) per the maximum recommended dose (4 tablets).

**DDI:** NSAIDS, Azathioprine or 6-mercaptopurine, Warfarin.

**Fertility, Pregnancy and Lactation:** Congenital malformations and other adverse outcomes were reported in infants born to mothers who were exposed to mesalazine during pregnancy. Mesalazine should be used during pregnancy only when the benefits outweigh the risks. Caution should be exercised if using Mesalazine while breast-feeding and only if the benefit outweighs the risks.

**Driving:** Negligible influence on driving.

**Undesirable Effects:** *Common (≥1/100 to <1/10):* Headache, Hypertension, Abdominal distension, Abdominal pain, Colitis, Diarrhoea, Dyspepsia, Vomiting, Flatulence, Nausea, Liver Function Test abnormal (e.g. ALT; AST, Bilirubin), Pruritus, Rash, Arthralgia, Back pain, Asthenia, Fatigue, Pyrexia.

**Overdosage:** Tinnitus, vertigo, headache, confusion, drowsiness, pulmonary oedema, dehydration as a result of sweating, diarrhoea and vomiting, hypoglycaemia, hyperventilation, disruption of electrolyte balance and blood-pH and hyperthermia.

**Storage condition:** Store below 30°C. Store in the original package in order to protect from moisture

**Name and Address of Product Registration Holder:** Takeda Malaysia Sdn Bhd, Unit TB-L13-1, Level 13, Tower B, Plaza 33, No. 1, Jalan Kemajuan, Seksyen 13, Petaling Jaya, 46200 Petaling Jaya, Selangor, Malaysia.

Further information is available on request.

Suspected Adverse events should be reported to Takeda at: AE.VMAPS@takeda.com

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