

- **UNLICENSED USE** *Maxolon*® tablets not licensed for use in children.

**IMPORTANT SAFETY INFORMATION**

MHRA/CHM ADVICE—METOCLOPRAMIDE: RISK OF NEUROLOGICAL ADVERSE EFFECTS—RESTRICTED DOSE AND DURATION OF USE (AUGUST 2013)

The benefits and risks of metoclopramide have been reviewed by the European Medicines Agency's Committee on Medicinal Products for Human Use, which concluded that the risk of neurological effects such as extrapyramidal disorders and tardive dyskinesia outweigh the benefits in long-term or high-dose treatment. To help minimise the risk of potentially serious neurological adverse effects, the following restrictions to indications, dose and duration of use have been made:

- In children aged 1–18 years, metoclopramide should only be used as a second-line option for prevention of delayed chemotherapy-induced nausea and vomiting and for treatment of established postoperative nausea and vomiting;
  - Use of metoclopramide is contra-indicated in children aged under 1 year;
  - Metoclopramide should only be prescribed for short-term use (up to 5 days);
  - Recommended dose is 100–150 micrograms/kg (max. 10 mg), repeated up to 3 times daily;
  - Intravenous doses should be administered as a slow bolus over at least 3 minutes;
  - Oral liquid formulations should be given via an appropriately designed, graduated oral syringe to ensure dose accuracy.
- This advice does not apply to unlicensed uses of metoclopramide (e.g. palliative care).

- **CONTRA-INDICATIONS** 3–4 days after gastrointestinal surgery · epilepsy · gastro-intestinal haemorrhage · gastro-intestinal obstruction · gastro-intestinal perforation · pheochromocytoma
- **CAUTIONS** Asthma · atopic allergy · bradycardia · cardiac conduction disturbances · children · may mask underlying disorders such as cerebral irritation · uncorrected electrolyte imbalance · young adults
- **INTERACTIONS** → Appendix 1: metoclopramide
- **SIDE-EFFECTS**  
**GENERAL SIDE-EFFECTS**
  - ▶ **Common or very common** Asthenia · depression · diarrhoea · drowsiness · hypotension · menstrual cycle irregularities · movement disorders · parkinsonism
  - ▶ **Uncommon** Arrhythmias · hallucination · hyperprolactinaemia · level of consciousness decreased
  - ▶ **Rare or very rare** Confusion · galactorrhoea · seizure
  - ▶ **Frequency not known** Atrioventricular block · blood disorders · cardiac arrest · gynaecomastia · hypertension · neuroleptic malignant syndrome · QT interval prolongation · shock · syncope · tremor
- **SPECIFIC SIDE-EFFECTS**
  - ▶ With parental use Anxiety · dizziness · dyspnoea · oedema · skin reactions · visual impairment
- **SIDE-EFFECTS, FURTHER INFORMATION** Metoclopramide can induce acute dystonic reactions involving facial and skeletal muscle spasms and oculogyric crises. These dystonic effects are more common in the young, especially girls and young women; they usually occur shortly after starting treatment with metoclopramide and subside within 24 hours of stopping it. Use of an antimuscarinic drug such as procyclidine will abort dystonic attacks.
- **PREGNANCY** Not known to be harmful.
- **BREAST FEEDING** Small amount present in milk; avoid.

- **HEPATIC IMPAIRMENT** Manufacturer advises caution in severe impairment (risk of accumulation).  
**Dose adjustments** Manufacturer advises dose reduction of 50% in severe impairment.
- **RENAL IMPAIRMENT**  
**Dose adjustments** Avoid or use small dose in severe impairment; increased risk of extrapyramidal reactions.
- **DIRECTIONS FOR ADMINISTRATION** Oral liquid preparation to be given via a graduated oral dosing syringe.
- **PATIENT AND CARER ADVICE** Counselling on use of pipette advised with oral solution.
- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: oral solution

**Solution for injection**▶ **Metoclopramide hydrochloride (Non-proprietary)**

**Metoclopramide hydrochloride 5 mg per 1 ml** Metoclopramide 10mg/2ml solution for injection ampoules | 5 ampoule [PoM] £1.31-£15.00 | 10 ampoule [PoM] £25.00 DT = £2.88

▶ **Maxolon** (Advanz Pharma)

**Metoclopramide hydrochloride 5 mg per 1 ml** Maxolon High Dose 100mg/20ml solution for injection ampoules | 10 ampoule [PoM] £26.68

**Oral solution**▶ **Metoclopramide hydrochloride (Non-proprietary)**

**Metoclopramide hydrochloride 1 mg per 1 ml** Metoclopramide 5mg/5ml oral solution sugar-free | 150 ml [PoM] £19.79 DT = £19.79

**Tablet**▶ **Metoclopramide hydrochloride (Non-proprietary)**

**Metoclopramide hydrochloride 10 mg** Metoclopramide 10mg tablets | 28 tablet [PoM] £1.80 DT = £0.88

▶ **Maxolon** (Advanz Pharma)

**Metoclopramide hydrochloride 10 mg** Maxolon 10mg tablets | 84 tablet [PoM] £5.24

**ANTIEMETICS AND ANTINAUSEANTS > NEUROKININ RECEPTOR ANTAGONISTS****Aprepitant**

11-Sep-2018

**● INDICATIONS AND DOSE**

**Adjunct treatment to prevent nausea and vomiting associated with moderately and highly emetogenic chemotherapy**

- ▶ **BY MOUTH**
- ▶ Child 6 months–11 years (body-weight 6 kg and above): (consult product literature)
- ▶ Child 12–17 years: Initially 125 mg, dose to be taken 1 hour before chemotherapy, then 80 mg once daily for 2 days, dose to be taken 1 hour before chemotherapy or in the morning if no chemotherapy is given, consult product literature for dose of concomitant 5HT<sub>3</sub>-antagonist (and corticosteroid if required)

- **CONTRA-INDICATIONS** Acute porphyrias p. 652
- **INTERACTIONS** → Appendix 1: aprepitant
- **SIDE-EFFECTS**
  - ▶ **Common or very common** Appetite decreased · asthenia · constipation · gastrointestinal discomfort · headache · hiccups
  - ▶ **Uncommon** Anaemia · anxiety · burping · dizziness · drowsiness · dry mouth · febrile neutropenia · gastrointestinal disorders · hot flush · malaise · nausea · palpitations · skin reactions · urinary disorders · vomiting
  - ▶ **Rare or very rare** Bradycardia · cardiovascular disorder · chest discomfort · cognitive disorder · conjunctivitis · cough · disorientation · euphoric mood · gait abnormal · hyperhidrosis · increased risk of infection · muscle spasms · muscle weakness · oedema · oropharyngeal pain · photosensitivity reaction · polydipsia · seborrhoea · severe cutaneous adverse reactions (SCARs) · sneezing ·