

● PATIENT AND CARER ADVICE

Driving and skilled tasks Drowsiness may affect performance of skilled tasks (e.g. driving or cycling); sedating effects enhanced by alcohol.

- **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

Oral solution

CAUTIONARY AND ADVISORY LABELS 2, 21

- ▶ **Zaditen** (CD Pharma Srl)

Ketotifen (as Ketotifen fumarate) 200 microgram per 1 ml Zaditen 1mg/5ml elixir sugar-free | 300 ml [PoM] £8.91 DT = £8.91

Tablet

CAUTIONARY AND ADVISORY LABELS 2, 21

- ▶ **Zaditen** (CD Pharma Srl)

Ketotifen (as Ketotifen fumarate) 1 mg Zaditen 1mg tablets | 60 tablet [PoM] £7.53 DT = £7.53

Promethazine hydrochloride

28-Nov-2019

● INDICATIONS AND DOSE

Symptomatic relief of allergy such as hay fever and urticaria | Insomnia associated with urticaria and pruritus

▶ BY MOUTH

- ▶ Child 2-4 years: 5 mg twice daily, alternatively 5-15 mg once daily, dose to be taken at night
- ▶ Child 5-9 years: 5-10 mg twice daily, alternatively 10-25 mg once daily, dose to be taken at night
- ▶ Child 10-17 years: 10-20 mg 2-3 times a day, alternatively 25 mg once daily, dose to be taken at night, increased if necessary to 25 mg twice daily
- ▶ Adult: 10-20 mg 2-3 times a day

▶ BY DEEP INTRAMUSCULAR INJECTION

- ▶ Adult: 25-50 mg (max. per dose 100 mg)

Emergency treatment of anaphylactic reactions

▶ BY SLOW INTRAVENOUS INJECTION

- ▶ Adult: 25-50 mg, to be administered as a solution containing 2.5 mg/mL in water for injections; maximum 100 mg per course

Sedation (short-term use)

▶ BY MOUTH

- ▶ Child 2-4 years: 15-20 mg
 - ▶ Child 5-9 years: 20-25 mg
 - ▶ Child 10-17 years: 25-50 mg
 - ▶ Adult: 25-50 mg
- ▶ BY DEEP INTRAMUSCULAR INJECTION
- ▶ Adult: 25-50 mg

Nausea | Vomiting | Vertigo | Labyrinthine disorders | Motion sickness

▶ BY MOUTH

- ▶ Child 2-4 years: 5 mg, to be taken at bedtime on night before travel, repeat following morning if necessary
- ▶ Child 5-9 years: 10 mg, to be taken at bedtime on night before travel, repeat following morning if necessary
- ▶ Child 10-17 years: 20-25 mg, to be taken at bedtime on night before travel, repeat following morning if necessary
- ▶ Adult: 20-25 mg, to be taken at bedtime on night before travel, repeat following morning if necessary

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: OVER-THE-COUNTER COUGH AND COLD MEDICINES FOR CHILDREN (APRIL 2009)

Children under 6 years should not be given over-the-counter cough and cold medicines containing promethazine.

● CAUTIONS

GENERAL CAUTIONS Epilepsy · prostatic hypertrophy (in adults) · pyloroduodenal obstruction · severe coronary artery disease · susceptibility to angle-closure glaucoma · urinary retention

SPECIFIC CAUTIONS

- ▶ With intravenous use Avoid extravasation with intravenous injection

- **INTERACTIONS** → Appendix 1: antihistamines, sedating

● SIDE-EFFECTS

GENERAL SIDE-EFFECTS Arrhythmia · blood disorder · confusion · dizziness · drowsiness · dry mouth · headache · hypotension · jaundice · movement disorders · palpitations · photosensitivity reaction · urinary retention · vision blurred

SPECIFIC SIDE-EFFECTS

- ▶ With oral use Agranulocytosis · angle closure glaucoma · anticholinergic syndrome · anxiety · insomnia · leucopenia · nasal congestion · nausea · rash · seizure · thrombocytopenia · tinnitus · tremor · vomiting
- ▶ With parenteral use Appetite decreased · epigastric discomfort · fatigue · haemolytic anaemia · hypersensitivity · muscle spasms · nightmare · restlessness · skin reactions

SIDE-EFFECTS, FURTHER INFORMATION Elderly patients are more susceptible to anticholinergic side-effects.

- **PREGNANCY** Most manufacturers of antihistamines advise avoiding their use during pregnancy; however, there is no evidence of teratogenicity. Use in the latter part of the third trimester may cause adverse effects in neonates such as irritability, paradoxical excitability, and tremor.

- **BREAST FEEDING** Most antihistamines are present in breast milk in varying amounts; although not known to be harmful, most manufacturers advise avoiding their use in mothers who are breast-feeding.

- **HEPATIC IMPAIRMENT** Manufacturer advises caution.

- **RENAL IMPAIRMENT** Use with caution.

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● PROFESSION SPECIFIC INFORMATION

Dental practitioners' formulary

Promethazine Hydrochloride Tablets 10 mg or 25 mg may be prescribed.

Promethazine Hydrochloride Oral Solution (elixir) 5 mg/5 mL may be prescribed.

- **LESS SUITABLE FOR PRESCRIBING** Promethazine is less suitable for prescribing for sedation.

- **EXCEPTIONS TO LEGAL CATEGORY** Prescription only medicine restriction does not apply to promethazine hydrochloride injection where administration is for saving life in emergency.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: oral suspension, oral solution

Solution for injection

EXCIPIENTS: May contain Sulfites

- ▶ **Phenergan** (Sanofi)

Promethazine hydrochloride 25 mg per 1 ml Phenergan 25mg/1ml solution for injection ampoules | 10 ampoule [PoM] £6.74 DT = £6.74

Oral solution

CAUTIONARY AND ADVISORY LABELS 2

EXCIPIENTS: May contain Sulfites

ELECTROLYTES: May contain Sodium

- ▶ **Phenergan** (Sanofi)

Promethazine hydrochloride 1 mg per 1 ml Phenergan 5mg/5ml elixir sugar-free | 100 ml [P] £2.85 DT = £2.85