

occur rarely, especially with high doses. Drowsiness may diminish after a few days of treatment and is considerably less of a problem with the newer antihistamines.

- **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.
- **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

● 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

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

Sedation in intensive care

▶ BY MOUTH, OR BY SLOW INTRAVENOUS INJECTION, OR BY DEEP INTRAMUSCULAR INJECTION

- ▶ Child 1 month–11 years: 0.5–1 mg/kg 4 times a day (max. per dose 25 mg), adjusted according to response
- ▶ Child 12–17 years: 25–50 mg 4 times a day, adjusted according to response

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

- **UNLICENSED USE** Not licensed for use for sedation in children under 2 years.

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE (MARCH 2008 AND FEBRUARY 2009) OVER-

THE-COUNTER COUGH AND COLD MEDICINES FOR CHILDREN

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

- **CONTRA-INDICATIONS** Neonate (due to significant antimuscarinic activity) · should not be given to children under 2 years, except on specialist advice, because the safety of such use has not been established
- **CAUTIONS**
GENERAL CAUTIONS Epilepsy · 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
- **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.
- **PATIENT AND CARER ADVICE**
Driving and skilled tasks Drowsiness may affect the performance of skilled tasks (e.g. cycling or driving); sedating effects enhanced by alcohol.
- **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.