

- **RENAL IMPAIRMENT** No information available—use with caution.
- **DIRECTIONS FOR ADMINISTRATION** Manufacturers advise that modified-release tablets should be taken with or after food. Licensed immediate-release formulations should be taken on an empty stomach, 2 hours before or 2 hours after food—intake with carbohydrate-rich meals may impair blood glucose control.

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

**Modified-release tablet**

CAUTIONARY AND ADVISORY LABELS 2, 21, 25

- ▶ **Melatonin (Non-proprietary)**  
**Melatonin 3 mg** Melatonin 3mg modified-release tablets | 120 tablet [PoM](#) [X](#)
- ▶ **Circadin** (Flynn Pharma Ltd)  
**Melatonin 2 mg** Circadin 2mg modified-release tablets | 30 tablet [PoM](#) £15.39 DT = £15.39
- ▶ **Slenyto** (Flynn Pharma Ltd)  
**Melatonin 1 mg** Slenyto 1mg modified-release tablets | 60 tablet [PoM](#) £41.20 DT = £41.20  
**Melatonin 5 mg** Slenyto 5mg modified-release tablets | 30 tablet [PoM](#) £103.00 DT = £103.00

**Tablet**

CAUTIONARY AND ADVISORY LABELS 2, 25

- ▶ **Melatonin (Non-proprietary)**  
**Melatonin 1 mg** Melatonin 1mg tablets | 90 tablet [PoM](#) [X](#)  
**Melatonin 3 mg** Melatonin 3mg tablets | 30 tablet [PoM](#) £15.95-£65.00 DT = £52.74  
**Melatonin 5 mg** Melatonin Extra Strength 5mg tablets | 60 tablet [PoM](#) [X](#)
- ▶ **VesPro** (Imported (United States))  
**Melatonin 500 microgram** VesPro Melatonin 500microgram tablets | 1000 tablet [PoM](#) [X](#)

**Oral solution**

CAUTIONARY AND ADVISORY LABELS 2

EXCIPIENTS: May contain Ethanol, propylene glycol, sorbitol

- ▶ **Melatonin (Non-proprietary)**  
**Melatonin 1 mg per 1 ml** Melatonin 1mg/ml oral solution sugar-free | 150 ml [PoM](#) £130.00 DT = £130.00

## Zolpidem tartrate

02-Feb-2019

**INDICATIONS AND DOSE****Insomnia (short-term use)**

- ▶ BY MOUTH
- ▶ Adult: 10 mg daily for up to 4 weeks, dose to be taken at bedtime, for debilitated patients, use elderly dose
- ▶ Elderly: 5 mg daily for up to 4 weeks, dose to be taken at bedtime

- **CONTRA-INDICATIONS** Acute respiratory depression · marked neuromuscular respiratory weakness · obstructive sleep apnoea · psychotic illness · severe respiratory depression · unstable myasthenia gravis

- **CAUTIONS** Avoid prolonged use (and abrupt withdrawal thereafter) · depression · elderly · history of alcohol abuse · history of drug abuse · muscle weakness · myasthenia gravis

**CAUTIONS, FURTHER INFORMATION**

- ▶ Elderly For hypnotic Z-drugs, prescription potentially inappropriate (STOPP criteria) in elderly (may cause protracted daytime sedation and/or ataxia). See also Prescribing in the elderly p. 33.

- **INTERACTIONS** → Appendix 1: zolpidem

**SIDE-EFFECTS**

- **Common or very common** Abdominal pain · anterograde amnesia · anxiety · back pain · diarrhoea · dizziness · fatigue · hallucination · headache · increased risk of infection · nausea · sleep disorders · vomiting

- ▶ **Uncommon** Confusion · diplopia · irritability
- ▶ **Frequency not known** Angioedema · behaviour abnormal · concentration impaired · delusions · depression · drug dependence · fall · gait abnormal · hepatic disorders · hyperhidrosis · level of consciousness decreased · libido disorder · muscle weakness · psychosis · respiratory depression · skin reactions · speech disorder · withdrawal syndrome

- **PREGNANCY** Avoid regular use (risk of neonatal withdrawal symptoms); high doses during late pregnancy or labour may cause neonatal hypothermia, hypotonia, and respiratory depression.

- **BREAST FEEDING** Small amounts present in milk—avoid.

- **HEPATIC IMPAIRMENT** Manufacturer advises caution in mild to moderate impairment (risk of decreased clearance); avoid in severe impairment.

**Dose adjustments** Manufacturer advises initial dose reduction to 5 mg daily in mild to moderate impairment.

- **RENAL IMPAIRMENT** Use with caution.

**PATIENT AND CARER ADVICE****Driving and skilled tasks** Drowsiness may persist the next day—leave at least 8 hours between taking zolpidem and performing skilled tasks (e.g. driving, or operating machinery); effects of alcohol and other CNS depressants enhanced.**NATIONAL FUNDING/ACCESS DECISIONS****NICE decisions**

- ▶ **Guidance on the use of zaleplon, zolpidem, and zopiclone for the short-term management of insomnia (April 2004)**

NICE TA77

Zolpidem is recommended for the short-term management of severe insomnia that interferes with normal daily life, and should be prescribed for short periods of time only.

[www.nice.org.uk/guidance/ta77](http://www.nice.org.uk/guidance/ta77)

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

**Tablet**

CAUTIONARY AND ADVISORY LABELS 19

- ▶ **Zolpidem tartrate (Non-proprietary)**  
**Zolpidem tartrate 5 mg** Zolpidem 5mg tablets | 28 tablet [PoM](#) £3.08 DT = £2.90 [CD4-1](#)  
**Zolpidem tartrate 10 mg** Zolpidem 10mg tablets | 28 tablet [PoM](#) £4.48 DT = £1.52 [CD4-1](#)
- ▶ **Stilnoct** (Sanofi)  
**Zolpidem tartrate 5 mg** Stilnoct 5mg tablets | 28 tablet [PoM](#) £1.10 DT = £2.90 [CD4-1](#)  
**Zolpidem tartrate 10 mg** Stilnoct 10mg tablets | 28 tablet [PoM](#) £1.00 DT = £1.52 [CD4-1](#)

## Zopiclone

02-Feb-2019

**INDICATIONS AND DOSE****Insomnia (short-term use)**

- ▶ BY MOUTH
- ▶ Adult: 7.5 mg once daily for up to 4 weeks, dose to be taken at bedtime
- ▶ Elderly: Initially 3.75 mg once daily for up to 4 weeks, dose to be taken at bedtime, increased if necessary to 7.5 mg daily

**Insomnia (short-term use) in patients with chronic pulmonary insufficiency**

- ▶ BY MOUTH
- ▶ Adult: Initially 3.75 mg once daily for up to 4 weeks, dose to be taken at bedtime, increased if necessary to 7.5 mg daily

- **CONTRA-INDICATIONS** Marked neuromuscular respiratory weakness · respiratory failure · severe sleep apnoea syndrome · unstable myasthenia gravis