

### ● PATIENT AND CARER ADVICE

**Driving and skilled tasks** May cause drowsiness, impair judgement and increase reaction time, and so affect ability to drive or perform skilled tasks; effects of alcohol increased. Moreover the hangover effects of a night dose may impair performance on the following day.

For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including benzodiazepines, see *Drugs and driving* under Guidance on prescribing p. 1.

F 224

29-Mar-2019

## Clobazam

### ● INDICATIONS AND DOSE

#### Adjunct in epilepsy

##### ► BY MOUTH

- Child 1 month–5 years: Initially 125 micrograms/kg twice daily, dose to be increased if necessary every 5 days, maintenance 250 micrograms/kg twice daily (max. per dose 500 micrograms/kg twice daily); maximum 30 mg per day
- Child 6–17 years: Initially 5 mg daily, dose to be increased if necessary at intervals of 5 days, maintenance 0.3–1 mg/kg daily, daily doses of up to 30 mg may be given as a single dose at bedtime, higher doses should be divided; maximum 60 mg per day

#### Monotherapy for catamenial (menstruation) seizures (usually for 7–10 days each month, just before and during menstruation) (under expert supervision) | Cluster seizures

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- **UNLICENSED USE** Not licensed for use in children under 6 years. Not licensed as monotherapy.

### IMPORTANT SAFETY INFORMATION

#### SAFE PRACTICE

Clobazam has been confused with clonazepam; care must be taken to ensure the correct drug is prescribed and dispensed.

- **CONTRA-INDICATIONS** Hyperkinesia · obsessive states · phobic states · respiratory depression
- **CAUTIONS** Muscle weakness · organic brain changes
- CAUTIONS, FURTHER INFORMATION** The effectiveness of clobazam may decrease significantly after weeks or months of continuous therapy.
- **INTERACTIONS** → Appendix 1: clobazam
- **SIDE-EFFECTS** Appetite decreased · consciousness impaired · constipation · drug abuse · dry mouth · fall · gait unsteady · libido loss · movement disorders · muscle spasms · nystagmus · respiratory disorder · severe cutaneous adverse reactions (SCARs) · skin reactions · speech impairment · weight increased
- **BREAST FEEDING** Benzodiazepines are present in milk, and should be avoided if possible during breast-feeding. **Monitoring** All infants should be monitored for sedation, feeding difficulties, adequate weight gain, and developmental milestones.

### ● RENAL IMPAIRMENT

**Dose adjustments** Start with small doses in severe impairment.

- **MONITORING REQUIREMENTS** Routine measurement of plasma concentrations of antiepileptic drugs is not usually justified, because the target concentration ranges are arbitrary and often vary between individuals. However, plasma drug concentrations may be measured in children with worsening seizures, status epilepticus, suspected noncompliance, or suspected toxicity. Similarly, haematological and biochemical monitoring should not be undertaken unless clinically indicated.

### ● PRESCRIBING AND DISPENSING INFORMATION

**Switching between formulations** Care should be taken when switching between oral formulations in the treatment of epilepsy. The need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with the patient or their carer, taking into account factors such as seizure frequency and treatment history.

Patients being treated for epilepsy may need to be maintained on a specific manufacturer's branded or generic clobazam product.

### ● PATIENT AND CARER ADVICE

Medicines for Children leaflet: Clobazam for preventing seizures [www.medicinesforchildren.org.uk/clobazam-preventing-seizures-0](http://www.medicinesforchildren.org.uk/clobazam-preventing-seizures-0)

### ● NATIONAL FUNDING/ACCESS DECISIONS

**NHS restrictions** Clobazam is not prescribable in NHS primary care except for the treatment of epilepsy; endorse prescription 'SLS'.

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

#### Oral suspension

CAUTIONARY AND ADVISORY LABELS 2, 8, 19

##### ► Clobazam (Non-proprietary)

**Clobazam 1 mg per 1 ml** Clobazam 5mg/5ml oral suspension sugar free sugar-free | 150 ml [PoM] £90.00 DT = £90.00 [CD4-1] sugar-free | 250 ml [PoM] £150.00 [CD4-1]

**Clobazam 2 mg per 1 ml** Clobazam 10mg/5ml oral suspension sugar free sugar-free | 150 ml [PoM] £95.00 DT = £95.00 [CD4-1] sugar-free | 250 ml [PoM] £158.33 [CD4-1]

##### ► Perizam (Rosemont Pharmaceuticals Ltd)

**Clobazam 1 mg per 1 ml** Perizam 1mg/ml oral suspension sugar-free | 150 ml [PoM] £90.00 DT = £90.00 [CD4-1]

**Clobazam 2 mg per 1 ml** Perizam 2mg/ml oral suspension sugar-free | 150 ml [PoM] £95.00 DT = £95.00 [CD4-1]

##### ► Tapclob (Martindale Pharmaceuticals Ltd)

**Clobazam 1 mg per 1 ml** Tapclob 5mg/5ml oral suspension sugar-free | 150 ml [PoM] £90.00 DT = £90.00 [CD4-1] sugar-free | 250 ml [PoM] £150.00 [CD4-1]

**Clobazam 2 mg per 1 ml** Tapclob 10mg/5ml oral suspension sugar-free | 150 ml [PoM] £95.00 DT = £95.00 [CD4-1] sugar-free | 250 ml [PoM] £158.34 [CD4-1]

##### ► Zacco (Thame Laboratories Ltd)

**Clobazam 1 mg per 1 ml** Zacco 5mg/5ml oral suspension sugar-free | 150 ml [PoM] £82.00 DT = £90.00 [CD4-1]

**Clobazam 2 mg per 1 ml** Zacco 10mg/5ml oral suspension sugar-free | 150 ml [PoM] £87.00 DT = £95.00 [CD4-1]

#### Tablet

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##### ► Clobazam (Non-proprietary)

**Clobazam 10 mg** Clobazam 10mg tablets | 30 tablet [PoM] £3.65 DT = £3.64 [CD4-1]

##### ► Frisium (Sanofi)

**Clobazam 10 mg** Frisium 10mg tablets | 30 tablet [PoM] £2.51 DT = £3.64 [CD4-1]