

Information for primary care — Clobazam (epilepsy)

<p>RAG Status – Green + Background/Summary information</p>
<p>Clobazam is a long-acting 1,5-benzodiazepine that has anticonvulsant as well as anxiolytic properties. The exact mechanism of action is not fully known, but is thought to bind to the benzodiazepine site of the gamma-aminobutyric acid type A (GABAA) receptor, which in turn potentiates the inhibitory effects of GABA.</p>
<p>Related NICE guidance</p>
<p>Specific NICE guidance is not available, but guidance on Epilepsies: diagnosis and management, NICE CG137 (January 2012, last updated: February 2016 https://www.nice.org.uk/guidance/cg137) recommends that adjunctive or ‘add-on’ therapy should only be considered when attempts at monotherapy with AEDs have not resulted in seizure freedom.</p>
<p>See manufacturer’s SPCs for full prescribing information) : https://www.medicines.org.uk/emc/search?q=%22Clobazam%22</p>
<p>Licensed indication</p>
<p>Clobazam is licensed for adjunctive therapy in the treatment of various epilepsies.</p>
<p>Dosage and administration</p>
<p>For 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.</p> <p>For Adult 20–30 mg daily then increased if necessary up to 60 mg daily.</p> <p>Tablets can be administered whole, or crushed and mixed in apple sauce. The 10 mg tablets can be divided into equal halves of 5 mg. Clobazam can be given with or without food</p> <p>Key points for safe use:</p> <ul style="list-style-type: none"> • Clobazam has been confused with clonazepam; care must be taken to ensure the correct drug is prescribed and dispensed. • MHRA/CHM advice: Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression (March 2020) <p>GP and specialist responsibilities</p> <ul style="list-style-type: none"> • Patient will be reviewed regularly by the specialist in secondary care until stable. Patient may then be transferred to GP care. • The GP will provide prescriptions for the patient in line with the instructions given by the specialist in secondary care. • The specialist team will provide advice and answer queries on the use of this drug and can be contacted on 0191 565 6256.

Contraindications
In patients with: hypersensitivity to clobazam, benzodiazepines or any of the excipients (see SPC); myasthenia gravis (risk of aggravation of muscle weakness); severe respiratory insufficiency (risk of deterioration); sleep apnoea syndrome (risk of deterioration) and severe hepatic insufficiencies (risk of precipitating encephalopathy). Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take the tablets as they contain lactose.
Cautions
Some depressed patients may experience a worsening of suicidal ideation. Some patients may exhibit abnormal thinking or behavioural changes. Risk of dependence increases with dose and duration of treatment. In patients with any history of drug or alcohol dependence (increased risk of development of dependence). Pregnancy and breastfeeding: Manufacturer advises avoid unless potential benefit outweighs risk — limited information available.
Side effects
Very common: fatigue and somnolence, especially at the beginning of treatment and when higher doses are used. Common: aggression, agitation, ataxia, constipation, decreased appetite, depression (pre-existing depression may be unmasked), disturbance in attention, dizziness, drug tolerance (especially during prolonged use), dry mouth, headache, irritability, nausea, restlessness, sedation, slow speech/dysarthria/ speech disorder (particularly with high doses or in long-term treatment, and are reversible), tremor.
Drug interactions
Clobazam with alcohol or CNS depressants is not recommended as the combination can increase drowsiness and reduce alertness. Clobazam plasma concentration may be increased by strong and moderate CYP2C19 inhibitors e.g. fluvoxamine, fluconazole, omeprazole. Addition of clobazam to established anticonvulsant medication may cause a change in plasma levels of these drugs. If used as an adjuvant in epilepsy the dose of clobazam and anticonvulsants may have to be adjusted (determined by monitoring the EEG and the plasma levels of the other drugs).
Monitoring
No specific monitoring of patients is required.
Cost
10 mg tablets, 30 = £3.75 5 mg/5 mL oral suspension sugar free, 150 mL = £90.00 10 mg/5 mL oral suspension sugar free, 150 mL = £95.00

References

1. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <<http://www.medicinescomplete.com>> Accessed: 26/10/20
2. Frisium 10 mg tablets SPC (updated: 7/4/20), Clobazam Wockhardt 1 mg/mL Oral Suspension (updated: .16/7/20) electronic Medicines Compendium (eMC). <http://www.medicines.org.uk/emc/>. Accessed: 26/10/20
3. Patsalos PN and St.Louis EK. The Epilepsy Prescriber's Guide to Antiepileptic Drugs, 3rd ed. Cambridge, Cambridge University Press; 2018

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