



## MONOGRAPH

# CLOBAZAM

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

### Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [DISCLAIMER](#)

**! HIGH RISK MEDICINE !**

### QUICKLINKS

<a href="#">Dosage/Dosage Adjustments</a>	<a href="#">Administration</a>	<a href="#">Compatibility</a>	<a href="#">Monitoring</a>
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### DRUG CLASS

Clobazam is a benzodiazepine/antiepileptic.<sup>1</sup>

Clobazam is a [High Risk Medicine](#).

cloBAZam may be confused with CLONazepam. Double check medication.

### INDICATIONS AND RESTRICTIONS

- Monotherapy or adjunctive therapy for generalised or partial seizures<sup>2</sup>
- Recurrent prolonged or repetitive (cluster) seizures<sup>3</sup>
- Lennox-Gastaut syndrome<sup>2</sup>
- Dravet syndrome<sup>2</sup>

### CONTRAINDICATIONS

- Hypersensitivity to clobazam or any component of the formulation<sup>2</sup>
- Acute pulmonary insufficiency, marked neuromuscular respiratory weakness, respiratory depression, sleep apnoea<sup>1, 4</sup>
- Obsessional states, phobic states<sup>4</sup>

- Unstable myasthenia gravis<sup>4</sup>

## PRECAUTIONS

- Hypersensitivity to other benzodiazepines<sup>5</sup>
- Concurrent use of drugs that cause central nervous system and respiratory depression<sup>5</sup>
- Hepatic and renal impairment<sup>2, 5</sup>
- Paradoxical reactions such as hyperactive or aggressive behaviour may occur<sup>2</sup>
- Avoid abrupt discontinuation with prolonged therapy<sup>5</sup>

## FORMULATIONS

Listed below are products available at Perth Children's Hospital (PCH), other formulations may be available, check with pharmacy if required:

- 10 mg tablets
- 1 mg/mL suspension

Imprest location: [Formulary One](#)

## DOSAGE & DOSAGE ADJUSTMENTS

**Round doses to the nearest quarter tablet (2.5mg) where possible.**

### Seizures or epilepsy:

- 2 to 12 years: Initially 0.1-0.25 mg/kg (max 5 mg) twice daily; dose may be titrated up to 0.5 mg/kg (max 20 mg) twice daily<sup>3</sup>
- 12 to 18 years: Initially 5–10 mg twice daily; dose may be titrated up to 20 mg twice daily<sup>2</sup>

Use the lowest effective dose.

Recommended interval between dose titration is 5 to 7 days.<sup>2, 3</sup> Shorter intervals may be used at the discretion of a Neurologist.

### Refractory Seizures:

- <2 years: Initially 0.5 to 1 mg/kg/day, usually given in divided doses twice daily (usual maximum 5 mg/day). May be increased up to a maximum of 10 mg/day.<sup>2</sup>
- ≥2 years: Initially 0.3 to 1 mg/kg/day, usually given in divided doses twice daily (usual maximum 20 mg/day). May be increased up to a maximum of 40 mg/day.<sup>2</sup>

### Recurrent prolonged or repetitive (cluster) seizures:

- 0.25 mg/kg stat. Repeat if necessary<sup>3</sup>

### Prophylaxis of recurrent febrile seizure during febrile illness:

- 0.25–0.5 mg/kg (max 5 mg), twice daily<sup>6,7</sup>

**Lennox-Gastaut syndrome (children ≥2 years):**

- ≤30 kg: Initially 5 mg once daily. Titrate according to response up to 10 mg twice daily<sup>2</sup>
- >30 kg: Initially 5 mg twice daily. Titrate according to response up to 20 mg twice daily<sup>2</sup>

**Dravet syndrome (>28 days old):**

- Initially 0.2 to 0.3 mg/kg/day, usually given in divided doses twice daily. Titrate up to common target range of 0.5 to 2 mg/kg/day.<sup>2</sup>

**Dosing in Overweight and Obese Children:**

- Calculate dose based on ideal body weight.

**Renal impairment:**

- [eGFR calculator](#)
- Commence with lower doses and use with caution in severe impairment (CrCl <30mL/min).<sup>1,2</sup>

**Hepatic impairment:**

- Avoid in severe impairment. In mild-to-moderate impairment consider using lower doses of a short-acting benzodiazepine instead to reduce risk of precipitating coma.<sup>1, 4</sup>

**ADMINISTRATION**

- Administer via enteral route, with or without food<sup>5</sup>
- Tablets may be crushed or dispersed in water before administration<sup>8</sup>

**MONITORING**

- Respiratory rate, sedation (intermittent)<sup>2,8</sup>
- Mental status (suicidality, depression, behavioural changes)<sup>2,8</sup>
- Liver function tests, renal function and complete blood count (if clinically indicated)<sup>2,8</sup>

**ADVERSE EFFECTS**

**Common:** Excessive sedation, drowsiness, light-headedness, hypersalivation, ataxia, slurred speech, visual disturbances<sup>1,2,4</sup>

**Infrequent:** Confusion, paradoxical excitation, aggression and hostility, anxiety, respiratory depression, headache, hypotension<sup>1,4</sup>

**Rare:** Stevens-Johnson syndrome, toxic epidermal necrolysis, urinary retention, blood disorders, transient elevated liver function tests, jaundice<sup>1</sup>

**STORAGE**

Clobazam is a Restricted Schedule 4 (S4R) medication and must be stored securely within an Automatic Dispensing Machine (ADM) as outlined in the [Schedule 8 and Restricted Schedule 4 Medication Policy](#).

Tablets: Store below 30°C <sup>8</sup>

Suspension: Store between 2°C to 8°C

## INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. [Clinical Pharmacology](#)), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

## REVERSAL OF OVERDOSE/OVERSEDDATION

[Flumazenil](#) can be used to reverse the effects of clobazam. Clinical areas must ensure they have access to flumazenil injection before administering clobazam.

*\*\*Please note: The information contained in this guideline is to assist with the preparation and administration of **cloBAZam**. Any variations to the doses recommended should be clarified with the prescriber prior to administration\*\**

## Related internal policies, procedures and guidelines

[High Risk Medicines Policy](#)




[Schedule 8 and Restricted Schedule 4 Medication Policy.](#)

[Flumazenil Monograph](#)

## References

1. Australian Medicines Handbook [Internet]. Australian Medicines Handbook. 2023 [cited 29/12/2023]. Available from: <https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/>.
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4. British National Formulary for Children: BMJ Group,  
Royal Pharmaceutical Society of Great Britain; 2023. Available from: <https://www.medicinescomplete-com.pklibresources.health.wa.gov.au/mc/bnfc/current/>.
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6. Offringa M, Newton R, Nevitt SJ, Katerina V. Prophylactic drug management for febrile seizures in children. The Cochrane database of systematic reviews. 2021 Jun 16;6:CD003031. PubMed PMID: 34131913. Epub 2021/06/16. eng.
7. Silberstein J. Clobazam dose for prevention of recurrent febrile seizure. In: Hong C, editor. 2017.
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