



## MONOGRAPH

# TEMOZOLOMIDE

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

Alkylating agent.<sup>1</sup>

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

Temozolomide is a [Cytotoxic Medicine](#).

**Emetogenic Rating:** Moderate. Refer to [Anti-cancer Therapy Induced Nausea and Vomiting \(AINV\) Management Guideline](#).

### INDICATIONS AND RESTRICTIONS

- Temozolomide can only be prescribed by oncologists or haematologists as per protocol for the treatment of malignancy.

**CONTRAINDICATIONS**

- Hypersensitivity to Temozolomide or any component of the formulation.<sup>1, 2</sup>
- Contraindicated in pregnancy and breastfeeding.<sup>2</sup>

**PRECAUTIONS**

- Use of temozolomide in combination with other alkylating agents or O<sup>6</sup>-alkylguanine-DNA alkyl transferases may increase the likelihood of myelosuppression and general toxicity.<sup>2</sup>
- Prophylaxis against PJP is recommended during combined treatment with temozolomide and radiotherapy.<sup>1</sup>
- Screen for Hepatitis B infection before use, discontinue use if patient has an active Hepatitis B infection.<sup>2</sup>

**FORMULATIONS**

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Temozolomide 5 mg, 20 mg, 100 mg, 140 mg and 180 mg capsules.<sup>1, 2</sup>

Imprest location: [Formulary One](#)

**DOSAGE & DOSAGE ADJUSTMENTS**

**Neonates:** [Refer to Neonatal Medication Protocols](#)

**Renal impairment:**

- Caution is recommended for severe impairment, however no specific guidelines exist.<sup>2</sup>
- [eGFR calculator](#)

**Hepatic impairment:**

- Caution is recommended for severe impairment, however no specific guidelines exist.<sup>2</sup>

**Treatment related toxicity:**

- Dose adjustment as per treatment protocol.

**ADMINISTRATION**

- Handle as [cytotoxic](#).
- Take on an empty stomach, at least an hour before food.<sup>1,2</sup>
- Swallow whole with a glass of water; do not open or chew the capsules.<sup>1,2</sup>
- Capsules may be mixed with apple juice in a closed system device to disperse.<sup>3</sup>

**MONITORING**

- Monitor complete blood count and liver function.<sup>1</sup>

## ADVERSE EFFECTS

**Common:** Constipation, nausea, vomiting, anorexia, alopecia, headache, seizure, fatigue<sup>2,3</sup>

**Infrequent:** Peripheral oedema, skin rash, pruritus, xeroderma, erythema of skin, diarrhea, dysphagia, dizziness, ataxia, hemiparesis, asthenia, fever, stomatitis, abdominal pain, dysgeusia, weight gain, platelet count decreased, white blood cell count decreased, lymphocyte count decreased, urinary incontinence or frequency, cough, dyspnoea, infection, anxiety, depression, insomnia, gait disturbance, amnesia, paraesthesia, drowsiness, visual disturbances, back pain, arthralgia/myalgia<sup>2,3</sup>

**Rare:** Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, hyperbilirubinemia, transaminitis, injection site reaction (IV formulation), interstitial pneumonitis, pancytopenia (may be prolonged), myelodysplastic syndrome, leukemia secondary to oncology chemotherapy, infections and infestations – other: Pneumocystis pneumonia, pulmonary fibrosis, anaphylaxis, allergic reaction, hepatotoxicity, cholestasis, anaemia, aplastic anaemia<sup>2,3</sup>

## STORAGE

Capsules - store below 25°C<sup>2</sup>

## 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.

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

## Related CAHS internal policies, procedures and guidelines

[Anti-cancer Therapy Induced Nausea and Vomiting Management](#)

[Antineoplastic \(Cytotoxic\) Agents](#)



## References

1. Bochner F RS. Australian Medicines Handbook Pty Ltd. [Online]. Australia: Pharmaceutical Society of Australia; 2023 [cited 13th September 2023]. Available from: [Temozolomide - Australian Medicines Handbook \(health.wa.gov.au\)](#).
2. MIMS Australia Pty Ltd. [Online]. St. Leonards, New South Wales: CMP Medica Australia Pty Ltd.; 2023 [cited 13th September 2023]. Available from: [MIMS | MIMS | Full Product Information \(health.wa.gov.au\)](#)

## References

3. Drug information for commercial agents used by the Children's Oncology Group [Online]. Children's Oncology Group; 2022 [cited 4th August 2023]. Available from: <https://www.cogmembers.org/files/disc/Pharmacy/CommercialAgentsMonographs.pdf>
4. Trissel LA; Yanping Z, Koontz SE. Temozolomide Stability in Extemporaneously Compounded Oral Suspensions. Int J Pharm Compounding; Sep/Oct 2006; 10, 5;(1):396-9

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