

Systemic Anti Cancer Treatment Protocol

Temozolomide

**PROTOCOL REF: MPHATEMOZ
(Version No: 1.0)**

Approved for use in:

Newly diagnosed Glioblastoma multiforme (after concurrent radiotherapy treatment – see separate protocol for concurrent temozolomide) in patients with WHO PS 0-1

Malignant glioma showing recurrence or progression after standard therapy

Dosage:

Drug	Dosage	Route	Frequency
Temozolomide	150mg/m ²	oral	Once daily for 5 days At Cycle 2, the dose is escalated to 200 mg/m ² , if tolerated

Supportive treatments:

Ondansetron 8mg orally daily for 5 days of chemotherapy (one hour before TMZ)

Domperidone 10mg tablets, three times a day when required

Administration:

Temozolomide capsules are to be swallowed whole with a glass of water on an empty stomach, 1 hour before or after meals.

Cycle 1:

Temozolomide 150 mg/m²/day every day for 5 days

Cycle is repeated at 28 day interval

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Cycle2 onwards:

If cycle 1 was well tolerated the dose can be escalated to 200mg/m²/day for 5 days

Treatment is continued for 6 cycles after concurrent radiotherapy or until disease progression/unacceptable toxicity for recurrent patients.

Extravasation risk:

Not applicable

Main Toxicities:

Myelosuppression (thrombocytopenia and neutropenia)

Anaemia

Tiredness and weakness (fatigue) during and after treatment

Alopecia

Nausea and vomiting

Anorexia

An itchy rash and dry skin– severe allergic rash occurs occasionally and requires discontinuation of temozolomide

Headaches

Constipation

Hepatotoxicity (rare fatal cases have been reported)

Loss of fertility

Pneumocystis carinii pneumonia

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Investigations:

	Pre	Cycle 1	Cycle 2	Cycle 3	Ongoing
Medical Assessment	X	X	X	X	Every cycle
Nursing Assessment		X	X	X	Every cycle
FBC	X	X	X	X	Every cycle
U&E & LFTs	X	X	X	X	Every cycle
MRI scan	X				Every 3 cycles
Informed Consent	X				
PS recorded	X	X	X	X	
Toxicities documented	X	X	X	X	
Weight recorded	X	X	X	X	Every cycle

Dose Modifications and Toxicity Management:

Toxicity	Defer for one week	Discontinue TMZ
Absolute neutrophil count	< 1.5 x 10 ⁹ /L	If dose reduction to 100 mg/m ² still results in unacceptable toxicity
Platelet count	< 100 x 10 ⁹ /L	
CTC non-haematological toxicity (except for alopecia, nausea, vomiting)	CTC Grade 3	If the same Grade 3 non-haematological toxicity (except for alopecia, nausea, vomiting) recurs after dose reduction

Dose modifications:

Dose level	TMZ dose (mg/m ² /day)	Remarks
-1	100	Reduction for prior toxicity
0	150	Dose during Cycle 1
1	200	Dose during Cycles 2 to 6 in absence of toxicity

Renal Impairment

No dose adjustment necessary

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Hepatic toxicity

Review concurrent medication – particularly anticonvulsants and consider their effect on LFTs

Stop temozolomide if progressive rise in transaminases or rise in bilirubin

References:

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Survival following adjuvant PCV or temozolomide for anaplastic astrocytoma

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