

Systemic Anti Cancer Therapy Protocol

## Oral Melphalan and Prednisolone MYELOMA

PROTOCOL REF: MPHAOPPM  
(Version No. 1.0)

### Approved for use in:

Treatment of myeloma in patients who are not candidates for autologous stem cell transplantation and who are treated with a palliative intent

### Dosage:

Drug	Dose	Route	Frequency
Melphalan	7mg/m <sup>2</sup>	PO	Daily on Days 1 to 4 of cycle
Prednisolone	20 to 60mg	PO	Daily on Days 1 to 4 of cycle

Every 4 to 6 weeks until plateau phase (paraprotein level stable for 3 months) then stop

### Administration:

- Take prednisolone in the morning with food to avoid sleep disturbance and gastric irritation.

### Emetogenic risk:

Low risk

### Supportive treatments:

- Allopurinol 300mg OD (first cycle only)
- Aciclovir 400mg BD
- Co-trimoxazole 480mg daily
- Omeprazole 20mg daily (at clinician discretion)

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- Fluconazole 50mg daily (at clinician discretion)

## Dosing in renal and hepatic impairment:

<b>Renal</b>	Melphalan	GFR: 30 – 50 mL/min	75% dose
		GFR: < 30mL/min	Clinical decision

<b>Hepatic</b>	Melphalan	No recommendations, if excess toxicity reduce dose for subsequent cycles	
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## Interactions:

No interactions of note with low dose oral melphalan.

## Main toxicities:

- Neutropenia, thrombocytopenia and anaemia
- Nausea, vomiting, diarrhoea
- Alopecia
- Temporary significant elevation of the blood urea has been seen in the early stages of melphalan therapy in myeloma patients with renal damage

## Investigations and treatment plan:

	Pre-initiation	Prior to each cycle	Ongoing
Informed Consent	x		
Clinical Assessment	x	x	Continue post treatment as indicated
SACT Assessment (to include PS and toxicities)	x	x	Every cycle
FBC, U&E & LFTs, bone profile	x	x	Every cycle
CrCl (Cockcroft and Gault)	x	x	Every cycle
Paraprotein, immunoglobulins, serum free light chains, beta 2 microglobulin, electrophoresis and immunofixation.	x	x	Every cycle (can be extended in stable patients at clinician discretion)
Virology screening (Hep B, Hep C, HIV)	x		
CT scan**	x		At the end of treatment and if clinically indicated
Blood glucose	x		If clinically indicated
Respiratory Rate			If clinically indicated
Weight recorded	x	x	Every cycle
Height recorded	x		

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## Dose Modifications and Toxicity Management:

### Haematological toxicity:

Proceed on day of treatment if:

ANC >1.0 x 10 <sup>9</sup> /L	Platelets >75 x 10 <sup>9</sup> /L
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If cytopenias are thought to be disease related then treatment may go ahead at clinician discretion.

Consider the following dose reductions for neutropenia / thrombocytopenia:

Haematological parameter			Dose reduction
ANC <1.0 x 10 <sup>9</sup> /L	Or	Platelets <50 x 10 <sup>9</sup> /L	Consider dose reduction
If prolonged ANC <0.5 x 10 <sup>9</sup> /L	Or	If prolonged platelets <25 x 10 <sup>9</sup> /L with bleeding	Reduce dose to 75% original dose

These haematological guidelines assume that patients are well with stable performance status, that other acute toxicities have resolved.

### Non - Haematological toxicity:

See Section entitled Dosing in Renal and Hepatic Impairment.

## References:

1. Summary of Product Characteristics, Melphalan 2mg tablets, Aspen. March 2014. Monograph available from: <http://www.medicines.org.uk>
2. Thames Valley Strategic Clinical Network. Myeloma Group. Oral Melphalan +/- Prednisolone v4.4. August 2017. Protocol available from: [Oxford Myeloma Group \(oxford-haematology.org.uk\)](http://oxford-haematology.org.uk)
3. South West Clinical Network. Melphalan and Prednisolone v1. January 2020. Protocol available from: [Quick Reference Guide - MRSA Topical Eradication \(england.nhs.uk\)](http://england.nhs.uk)
4. Krens S D, Lassche, Jansman G F G A, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment. Lancet Oncol 2019; 20: e201–08

## Circulation/Dissemination

Date added into Q-Pulse	26 <sup>th</sup> January 2023
Date document posted on the Intranet	N/A

## Version History

Date	Version	Author name and designation	Summary of main changes
September 2022	1.0	<b>Jade Marsh</b> Advanced HO Pharmacist	V1.0 New Regimen Protocol

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