## Regimen: Temozolomide and Radiotherapy

### Indication
Newly diagnosed glioblastoma multiforme (GBM) in adult patients with a WHO performance status of 0 or 1 (NICE TA121).

### Regimen details

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 42</td>
<td>Temozolomide</td>
<td>75 mg/m² once daily during the 6 weeks of radiotherapy</td>
<td>PO</td>
</tr>
</tbody>
</table>

### Administration
Temozolomide hard capsules are available as 5mg, 20mg, 100mg, 140mg, 180mg, and 250mg capsules. Capsules should be taken on an empty stomach, swallowed whole with a glass of water approximately 60 minutes before radiotherapy. Capsules must **NOT** be opened or chewed. If vomiting occurs after the dose is administered, a second dose should not be administered that day.

### Frequency
A single 6-week course

### Extradisation
N/A

### Premedication
5HT₃-antagonist once daily 30 mins prior to temozolomide days 1 to 3 only. Continued beyond this only if clinically indicated.

### Emetogenicity
This regimen has low emetogenic potential – refer to local protocol.

### Additional recommended supportive medication
PCP prophylaxis throughout treatment e.g. co-trimoxazole 480mg bd, three times a week.

### Pre-treatment evaluations
- **FBC**: Baseline – results valid for 14 days
- **U+E**: Baseline – results valid for 14 days
- **LFT**: Baseline – results valid for 14 days

### Regular investigations
- **FBC**: Weekly during treatment
- **U+E**: Weekly during treatment
- **LFT**: Weekly during treatment

### Standard limits for administration to go ahead – if blood results not within range, authorisation to administer must be given by prescriber/consultant

- **Neutrophil count**: > 1.0 x 10⁹/L
- **Platelet count**: > 100 x 10⁹/L

### Dose modifications
No dose reductions will be made in this phase of the patient’s treatment. If treatment has to be interrupted, missed doses will be omitted and the radiotherapy continued.

<table>
<thead>
<tr>
<th>Haematological toxicity</th>
<th>Neutrophils</th>
<th>Platelets</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5-1 x 10⁹/L OR 50-100 x 10⁹/L</td>
<td>Interrupt temozolomide therapy for 1 week (and continue with radiotherapy).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;0.5 x 10⁹/L OR &lt;50 x 10⁹/L</td>
<td>If FBC has recovered after 1 week, resume temozolomide at full dose.</td>
<td></td>
</tr>
</tbody>
</table>

### Renal impairment
No dose reduction required.
### Hepatic impairment

No dose reduction required. Caution recommended in patients with severe hepatic impairment.

### NCI Common toxicity criteria

See above under ‘Dose modifications’

#### Adverse effects

<table>
<thead>
<tr>
<th>Rare but serious side effects</th>
<th>Frequently occurring side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thromboembolism</td>
<td>Nausea or vomiting</td>
</tr>
<tr>
<td>Pneumonitis / dyspnoea</td>
<td>Fatigue</td>
</tr>
<tr>
<td>Hypersensitivity and allergic reactions</td>
<td>Anorexia, weight loss</td>
</tr>
<tr>
<td>Myopathy</td>
<td>Rash</td>
</tr>
<tr>
<td>Teratogenicity</td>
<td>Constipation, diarrhoea</td>
</tr>
<tr>
<td>Infertility</td>
<td>Seizures, headache</td>
</tr>
<tr>
<td>Opportunistic infections, including PCP, Herpes simplex and oral candidiasis</td>
<td>Arthralgia / myalgia</td>
</tr>
<tr>
<td></td>
<td>Myelosupression</td>
</tr>
<tr>
<td></td>
<td>Stomatitis/mucositis</td>
</tr>
<tr>
<td>Other</td>
<td>Raised liver enzymes; hearing impairment; anxiety; depression; alopecia</td>
</tr>
</tbody>
</table>

#### Significant drug interactions

**Sodium valproate:** co-administration may decrease clearance of Temozolomide

**Other**

<table>
<thead>
<tr>
<th>Significant drug interactions – the contents of the table indicate the adverse effects that should be documented on consent to treatment forms</th>
</tr>
</thead>
</table>

| Sodium valproate: co-administration may decrease clearance of Temozolomide |

#### Comments

Contra-indicated in patients hypersensitive to dacarbazine (DTIC)

#### Cumulative Doses

N/A

#### References


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