Maklumat tambahan indikasi untuk upload pada laman web
Year 2016
Products Approved For Additional Indication (DCA 301 – 30 Jun 2016)

<table>
<tr><th>NO</th><th>PRODUCT
(ACTIVE INGREDIENT)</th><th>ADDITIONAL INDICATION</th><th>MARKETING AUTHORIZATION HOLDER</th></tr>
<tr>
<td>1.</td>
<td>1.1 VELCADE (Bortezomib) for Injection
[Bortezomib 3.5 mg]

1.2 Velcade 1.0 mg for Injection
[Bortezomib 1.0 mg]</td>
<td>
➢ Indication:

VELCADE (bortezomib) for Injection is indicated for the treatment of patients with mantle cell lymphoma.

➢ Posology:

Dosage in Previously Untreated Mantle Cell Lymphoma
VELCADE (1.3 mg/m^2) is administered intravenously in combination with intravenous rituximab, cyclophosphamide, doxorubicin and oral prednisone (VcR-CAP) for six 3-week treatment cycles as shown in Table 3. VELCADE is administered first followed by rituximab. VELCADE is administered twice weekly for two weeks (Day 1, 4, 8, and 11) followed by a 10-day rest period on Days 12-21. For patients with a response first documented at cycle 6, two additional VcR-CAP cycles are recommended. At least 72 hours should elapse between consecutive doses of VELCADE.

Table 3: Dosage Regimen for Patients with Previously Untreated Mantle Cell Lymphoma
<table>
<tr><td colspan="9">Twice Weekly VELCADE (Six 3-Week Cycles)[a]</td></tr>
<tr><td>Week</td><td colspan="5">1</td><td colspan="2">2</td><td>3</td></tr>
<tr><td>VELCADE (1.3 MG/M^2)</td><td>Day 1</td><td>--</td><td>--</td><td>Day 4</td><td>--</td><td>Day 8</td><td>Day 11</td><td>Rest period</td></tr>
<tr><td>Rituximab (375 mg/m^2) Cyclophosphamide 750 mg/m^2) Doxorubicin (50 mg/m^2)</td><td>Day 1</td><td>--</td><td>--</td><td></td><td></td><td>--</td><td>--</td><td>Rest period</td></tr>
<tr><td>Prednisone (100 mg/m^2)</td><td>Day 1</td><td>Day 2</td><td>Day 3</td><td>Day 4</td><td>Day 5</td><td>--</td><td>--</td><td>Rest period</td></tr>
</table>
[a] Dosing may continue for 2 more cycles (for a total of 8 cycles) if response is first
</td>
<td>JOHNSON & JOHNSON SDN. BHD.
Lot 3 & 5, Jalan Tandang,
46050 Petaling Jaya, Selangor</td>
</tr>
</table>

seen at cycle 6.

Dose Modification Guidelines for VELCADE When Given in Combination with Rituximab, Cyclophosphamide, Doxorubicin and Prednisone
Prior to the first day of each cycle (other than Cycle 1):

- *Platelet count should be at least 100 x 10^9/L and absolute neutrophil count (ANC) should be at least 1.5 x 10^9/L*
- *Hemoglobin should be at least 8 g/dL (at least 4.96 mmol/L)*
- *Non-hematologic toxicity should have recovered to Grade 1 or baseline*

Interrupt VELCADE treatment at the onset of any Grade 3 hematologic or non-hematological toxicities, excluding neuropathy [see Table 5 and Warnings and Precautions (5)]. For dose adjustments, see Table 4 below:

Table 4: Dose Modifications on day 4, 8, and 11 during Cycles of Combination VELCADE, Rituximab, Cyclophosphamide, Doxorubicin and Prednisone Therapy

Toxicity	*Dose modification or delay*
Hematological toxicity	
• *Grade 3 or higher neutropenia, or a platelet count not at or above 25 x 10^9/L*	*Withhold VELCADE therapy for up to 2 weeks until the patient has an ANC at or above 0.75 x 10^9/L and a platelet count at or above 25 x 10^9/L.* • *If, after VELCADE has been withheld, the toxicity does not resolve, discontinue VELCADE.* • *If toxicity resolves such that the patient has an ANC at or above 0.75 x 10^9/L and a platelet count at or above 25 x 10^9/L, VELCADE dose should be reduced by 1 dose level (from 1.3 mg/m^2 to 1 mg/m^2, or from 1 mg/m^2 to 0.7 mg/m^2)*
Grade 3 or higher non-hematological toxicities	*Withhold VELCADE therapy until symptoms of the toxicity have resolved to Grade 2 or better. Then, VELCADE may be reinitiated with one dose level reduction (from 1.3 mg/m^2 to 1 mg/m^2, or from 1 mg/m^2 to 0.7 mg/m^2).* *For VELCADE-related neuropathic pain and/or peripheral neuropathy, hold or modify VELCADE as outlined in Table 5.*

		For information concerning rituximab, cyclophosphamide, doxorubicin and prednisone, see manufacturer's prescribing information. *Dosage and Dose Modifications for Relapsed Multiple Myeloma and Relapsed Mantle Cell Lymphoma* *VELCADE (1.3 mg/m^2/dose) is administered twice weekly for 2 weeks (Days 1, 4, 8, and 11) followed by a 10-day rest period (Days 12-21). For extended therapy of more than 8 cycles, VELCADE may be administered on the standard schedule or, for relapsed multiple myeloma, on a maintenance schedule of once weekly for 4 weeks (Days 1, 8, 15, and 22) followed by a 13-day rest period (Days 23 to 35). At least 72 hours should elapse between consecutive doses of VELCADE.* *Patients with multiple myeloma who have previously responded to treatment with VELCADE (either alone or in combination) and who have relapsed at least 6 months after their prior VELCADE therapy may be started on VELCADE at the last tolerated dose. Retreated patients are administered VELCADE twice weekly (Days 1, 4, 8, and 11) every three weeks for a maximum of 8 cycles. At least 72 hours should elapse between consecutive doses of VELCADE. VELCADE may be administered either as a single agent or in combination with dexamethasone*.	