Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 335 – 30 Mei 2019)

<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 REVLIMID (Lenalidomide) Capsules 5mg
[Lenalidomide 5 mg]

1.2 REVLIMID (Lenalidomide) Capsules 10mg
[Lenalidomide 10 mg]

1.3 REVLIMID (Lenalidomide) Capsules 15mg
[Lenalidomide 15 mg]

1.4 REVLIMID (Lenalidomide) Capsules 25mg
[Lenalidomide 25 mg]</td><td>➢ Indication:

Revlimid® as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.

➢ Posology:

<u>Newly diagnosed multiple myeloma (NDMM)</u>
• Lenalidomide maintenance in patients who have undergone autologous stem cell transplantation (ASCT)

Lenalidomide maintenance should be initiated after adequate haematologic recovery following ASCT in patients without evidence of progression. Lenalidomide must not be started if the Absolute Neutrophil Count (ANC) is < 1.0 x 10^9/L, and/or platelet counts are < 75 x 10^9/L.

Recommended dose
The recommended starting dose is lenalidomide 10 mg orally once daily continuously (on days 1 to 28 of repeated 28-day cycles) given until disease progression or intolerance. After 3 cycles of lenalidomide maintenance, the dose can be increased to 15 mg orally once daily if tolerated.

• Dose reduction steps
<table><tr><th></th><th>Starting dose (10 mg)</th><th>If dose increased (15 mg) [a]</th></tr><tr><td>Dose level -1</td><td>5 mg</td><td>10 mg</td></tr><tr><td>Dose level -2</td><td>5 mg (days 1-21 every 28 days)</td><td>5 mg</td></tr></table></td><td>CELGENE SDN. BHD.
Lot 6.05, Level 6, KPMG Tower 8
First Avenue, Bandar Utama,
47800 Petaling Jaya, Selangor</td></tr>
</table>

Dose level -3	*Not applicable*	*5 mg (days 1-21 every 28 days)*
	Do not dose below 5 mg (days 1-21 every 28 days)	

[a] *After 3 cycles of lenalidomide maintenance, the dose can be increased to 15 mg orally once daily if tolerated.*

- *Thrombocytopenia*

When platelets	*Recommended course*
Fall to < 30 x 10^9/L *Return to ≥ 30 x 10^9/L*	*Interrupt lenalidomide treatment* *Resume lenalidomide at dose level -1 once daily*
For each subsequent drop below 30 x 10^9/L *Return to ≥ 30 x 10^9/L*	*Interrupt lenalidomide treatment* *Resume lenalidomide at next lower dose level once daily*

- *Neutropenia*

When neutrophils	*Recommended course* [a]
Fall to < 0.5 x 10^9/L	*Interrupt lenalidomide treatment*
Return to ≥ 0.5 x 10^9/L	*Resume lenalidomide at dose level -1 once daily*
For each subsequent drop below < 0.5 x 10^9/L *Return to ≥ 0.5 x 10^9/L*	*Interrupt lenalidomide treatment* *Resume lenalidomide at next lower dose level once daily.*

[a] *At the physician's discretion, if neutropenia is the only toxicity at any dose level, add granulocyte colony stimulating factor (G-CSF) and maintain the dose level of lenalidomide*

<table>
<tr>
<td>2.</td>
<td>2.1 BLINCYTO (BLINATUMOMAB) FOR INJECTION 35 MCG/VIAL
[Blinatumomab 35 mcg/vial]</td>
<td>
➢ Indication:

MRD-positive B-cell Precursor ALL
BLINCYTO is indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults.
This indication is approved based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Relapsed or Refractory B-cell Precursor ALL
BLINCYTO is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

➢ Posology:

Treatment of MRD-positive B-cell Precursor ALL
• A treatment course consists of 1 cycle of BLINCYTO for induction followed by up to 3 additional cycles for consolidation.
• A single cycle of treatment of BLINCYTO induction or consolidation consists of 28 days of continuous intravenous infusion followed by a 14 day treatment free interval (total 42 days).
• See Table 1 for the recommended dose by patient weight and schedule. Patients greater than or equal to 45 kg receive a fixed dose.

Table 1. Recommended BLINCYTO Dosage and Schedule for the Treatment of MRD-positive B-cell Precursor ALL
<table>
<tr><th>Cycle</th><th>Patient Weight Greater Than or Equal to 45 kg (Fixed-dose)</th></tr>
<tr><td><u>Induction Cycle 1</u>
Days 1-28
Days 29-42</td><td>28 mcg/day

14-day treatment-free interval</td></tr>
</table>
</td>
<td>ZUELLIG PHARMA SDN. BHD.
No. 15, Persiaran Pasak Bumi, Sek U8
Perindustrian Bukit Jelutong
40150 Shah Alam, Selangor</td>
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</table>

Consolidation *Cycles 2-4* *Days 1-28* *Days 29-42*	 *28 mcg/day* *14-day treatment-free interval*

- *Hospitalization is recommended for the first 3 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiations (e.g., if treatment is interrupted for 4 or more hours), supervision by a healthcare professional or hospitalization is recommended.*
- *Intrathecal chemotherapy prophylaxis is recommended before and during Blincyto therapy to prevent central nervous system ALL relapse.*
- *Premedicate with prednisone or equivalent for MRD-positive B-cell Precursor ALL*
  o For adult patients, premedicate with prednisone 100 mg intravenously or equivalent (e.g., dexamethasone 16 mg) 1 hour prior to the first dose of BLINCYTO in each cycle.
- *For administration of BLINCYTO:*
  o See Section 2.5 for infusion over 24 hours or 48 hours.

Treatment of Relapsed or Refractory B-cell Precursor ALL

- *A treatment course consists of up to 2 cycles of BLINCYTO for induction followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy.*
- *A single cycle of treatment of BLINCYTO induction or consolidation consists of 28 days of continuous intravenous infusion followed by a 14-day treatment-free interval (total 42 days).*
- *A single cycle of treatment of BLINCYTO continued therapy consists of 28 days of continuous intravenous infusion followed by a 56-day treatment-free interval (total 84 days).*
- *See Table 2 for the recommended dose by patient weight and schedule. Patients greater than or equal to 45 kg receive a fixed-dose and for patients less than 45 kg, the dose is calculated using the patient's body surface area (BSA).*

Table 2. Recommended BLINCYTO Dosage and Schedule for the Treatment of Relapsed or Refractory B-cell Precursor ALL

Cycle	***Patient Weight Greater Than or Equal to 45 kg (Fixed-dose)***	***Patient Weight Less Than 45 kg (BSA-based dose)***
<u>Induction Cycle 1</u> *Days 1-7* *Days 8-28* *Days 29-42*	*9 mcg/day* *28 mcg/day* *14-day treatment-free interval*	*5 mcg/m^2/day (not to exceed 9 mcg/day)* *15 mcg/m^2 /day (not to exceed 28 mcg/day)* *14-day treatment-free interval*
<u>Induction Cycle 2</u> *Days 1-28* *Days 29-42*	*28 mcg/day* *14-day treatment-free interval*	*15 mcg/m^2 /day (not to exceed 28 mcg/day)* *14-day treatment-free interval*
<u>Consolidation Cycles 3-5</u> *Days 1-28* *Days 29-42*	*28 mcg/day* *14-day treatment-free interval*	*15 mcg/m^2 /day (not to exceed 28 mcg/day)* *14-day treatment-free interval*
<u>Continued Therapy Cycles 6-9</u> *Days 1-28* *Days 29-84*	*28 mcg/day* *56-day treatment-free interval*	*15 mcg/m^2 /day (not to exceed 28 mcg/day)* *56-day treatment-free interval*

- *Hospitalization is recommended for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (eg, if treatment is interrupted for 4 or more hours), supervision by a healthcare professional or hospitalization is recommended.*
- *Intrathecal chemotherapy prophylaxis is recommended before and during Blincyto therapy to prevent central nervous system ALL relapse.*
- *Premedicate with dexamethasone*
  o For adult patients, premedicate with 20 mg dexamethasone 1

		hour prior to the first dose of BLINCYTO of each cycle, prior to a step dose (such as Cycle 1 day 8), and when restarting an infusion after an interruption of 4 or more hours. *o For pediatric patients, premedicate with 5 mg/m^2 of dexamethasone, to a maximum dose of 20 mg prior to the first dose of BLINCYTO in the first cycle, prior to a step dose (such as Cycle 1 day 8), and when restarting an infusion after an interruption of 4 or more hours in the first cycle.* • *For administration of BLINCYTO:* *o See Section 2.5 for infusion over 24 hours or 48 hours.*	
3.	3.1 **Vaxigrip Tetra, Suspension for Injection in Pre-filled Syringe** [Each dose of 0.5ml contains: Influenza virus (inactivated, split) of the following strains: • A/California/7/2009 (NYMC X-179A) (H1N1) 15 mcg HA* • A/Texas/50/2012 (NYMC X-223A) (H3N2) 15 mcg HA* • B/Massachusetts/2/2012 (Yamagata lineage) 15 mcg HA* • B/Brisbane/60/2008 (Victoria lineage) 15 mcg HA* * haemagglutinin]	➢ Indication: *Vaxigrip Tetra is indicated for active immunisation of adults and children from **6 months** of age and older for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine.* *The use of Vaxigrip Tetra should be based on official recommendations.* ➢ Posology: *Based on clinical experience with the trivalent vaccine, annual revaccination with influenza vaccine is recommended given the duration of immunity provided by the vaccine and because circulating strains of influenza virus might change from year to year.* *Adults: one dose of 0.5 ml.* *<u>Paediatric population</u>* • *Children from **6 months** to 17 years of age: one dose of 0.5 ml.* • *For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 ml should be given after an interval of at least 4 weeks.* • *Children less than **6 months** of age: the safety and efficacy of Vaxigrip Tetra have not been established.*	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18 Tower B, Plaza 33 No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

		No data are available. *<u>Method of administration</u>* *The vaccine should be given by intramuscular or subcutaneous injection.* *The* ***preferred site for intramuscular injection is the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults.***	