Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 413, 2 Oktober 2025

Products approved for additional indication (DCA 413 – 2 October 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	BRIDION 100MG/ML SOLUTION FOR INJECTION [Sugammadex 100mg/ml]	**INDICATION :** BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adult and pediatric patients undergoing surgery. **POSOLOGY :** Preparation of dilution for pediatric use: Bridion 100 mg/mL may be diluted to a concentration of 10 mg/mL, using 0.9% sodium chloride injection, USP, to increase the accuracy of dosing in the pediatric population. • To prepare the required dose, aseptically transfer all the contents of the 2 mL vial of Bridion 2-mL single-dose vials containing 200 mg sugammadex (100 mg/mL) to a bottle (or intravenous bag) containing 18 mL of 0.9% sodium chloride injection, to achieve a final concentration of 10 mg/mL sugammadex. The diluted solution should be used immediately. • Bridion injection is a single-dose sterile solution without preservatives. Discard any unused portion from the vial. Pediatric population (birth and older for rocuronium and vecuronium) : Bridion 100 mg/ml may be diluted to 10 mg/ml to increase the accuracy of dosing in the pediatric population **Routine reversal:** A dose of 4 mg/kg sugammadex is recommended for reversal of rocuronium or vecuronium induced blockade if recovery has reached at least 1-2 post-tetanic counts (PTC) and there are no twitch responses to train-of-four (TOF) stimulation. A dose of 2 mg/kg is recommended for reversal of rocuronium or vecuronium induced blockade at reappearance of T_2	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Immediate reversal: Immediate reversal has not been investigated in the pediatric population. Method of administration Sugammadex should be administered intravenously as a single bolus injection. The bolus injection should be given rapidly, within 10 seconds, into an existing intravenous line. Sugammadex has only been administered as a single bolus injection in clinical trials.	

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<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr>
<td>2.</td>
<td>Jakavi 10mg Tablets

[Ruxolitinib phosphate 13.2mg (corresponding to 10mg of ruxolitinib free base)]

Jakavi 15mg Tablets

[Ruxolitinib phosphate 19.8mg (corresponding to 15mg of ruxolitinib free base)]

Jakavi 20mg Tablets

[Ruxolitinib phosphate 26.4mg (corresponding to 20mg of ruxolitinib free base)]

Jakavi 5mg Tablets

[Ruxolitinib phosphate 6.6mg (corresponding to 5mg of ruxolitinib free base)]</td>
<td>INDICATION :

<u>Graft versus host disease (GvHD)</u>

Jakavi is indicated for the treatment of adult and paediatric patients aged 6 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

POSOLOGY :

<u>Graft versus host disease (GvHD)</u>

The recommended starting dose of Jakavi in acute and chronic GvHD is based on age (see Table 2):

Table 2 Starting doses in graft versus host disease (GvHD) is 10 mg given orally twice daily.
<table>
<tr><th>Age group</th><th>Starting dose</th></tr>
<tr><td>12 years old and above

6 years to less than 12 years old</td><td>10 mg twice daily

5 mg twice daily</td></tr>
</table>
Removal of the following statement:

In paediatric patients (12 years of age and older) with GvHD, the safety and efficacy of Jakavi are supported by evidence from the randomised phase 3 studies REACH2 and REACH3. The Jakavi dose in paediatric patients with GvHD aged 12 years and older is the same as in adults. The safety and efficacy of Jakavi have not been established in patients less than 12 years of age.</td>
<td>NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
Level 18, Imazium,
No.8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor.</td>
</tr>
</table>

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<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>3.</td><td>Darzalex Faspro 1,800 mg solution for injection

[Daratumumab 120 mg/mL]</td><td>
INDICATION :

Multiple Myeloma

DARZALEX FASPRO is indicated for the treatment of adult patients with multiple myeloma:
• in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant

POSOLOGY :

The DARZALEX FASPRO dosing schedule in Table 4 is for combination therapy with bortezomib, lenalidomide and dexamethasone (4-week cycle regimens) for treatment of newly diagnosed multiple myeloma patients eligible for ASCT.

Table 4: DARZALEX FASPRO dosing schedule in combination with bortezomib, lenalidomide and dexamethasone ([VRd; 4-week cycle dosing regimen)
<table>
<tr><td>Treatment phase</td><td>Weeks</td><td>Schedule</td></tr>
<tr><td rowspan="2">Induction</td><td>Week 1 to 8</td><td>Weekly (total of 8 doses)</td></tr>
<tr><td>Weeks 9 to 16[a]</td><td>Every two weeks (total of 4 doses)</td></tr>
<tr><td colspan="3">Stop for high dose chemotherapy and ASCT</td></tr>
<tr><td>Consolidation</td><td>Weeks 17 to 24[b]</td><td>Every two weeks (total of 4 doses)</td></tr>
<tr><td>Maintenance</td><td>Week 25 onwards until disease progression[c]</td><td>Every four weeks</td></tr>
</table>
</td><td>JOHNSON & JOHNSON SDN. BHD.
Level 8, The Pinnacle,
Persiaran Lagoon,
Bandar Sunway,
46150 Petaling Jaya,
Selangor.</td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		[a] First dose of the every-2-week dosing schedule is given at Week 9 [b] Week 17 corresponds to re-initiation of treatment following recovery from ASCT [c] Discontinuation daratumumab for patients who have achieved MRD negativity that is sustained for 12 months and have been treated on maintenance for at least 24 months For dosing instructions of medicinal products administered with DARZALEX FASPRO, see Clinical Studies and manufacturer's prescribing information.	