Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 422, 7 Julai 2026

Products approved for additional indication (DCA 422 – 7 July 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Pamorelin Powder for Suspension for Injection 3.75 mg [Triptorelin Embonate 3.75mg]	**INDICATION:** Pamorelin 3.75 mg is indicated for the pituitary down-regulation in the context of assisted reproduction technology. **POSOLOGY:** Pituitary down-regulation in the context of assisted reproduction technology One intramuscular injection of Pamorelin 3.75 mg administered either in the early follicular phase, usually on the 2nd day of the menstrual cycle, or in the mid-luteal phase, usually on the 21st day of the previous cycle. In general, the stimulation by gonadotrophins should be performed when the plasma levels of oestrogens are consistent with ovarian suppression, usually less than 50 pg/ml around the 15th day of the cycle.	**ORIENT EUROPHARMA (M) SDN BHD** E-08, Garden Shoppe, One City, Jalan USJ 25/1C, 47650 Subang Jaya, Selangor.
2.	Lenvima 4 mg Hard Capsules [Lenvatinib mesilate 4.90mg (equivalent to 4mg lenvatinib)]	**INDICATION:** LENVIMA is indicated for the treatment of adult patients with previously treated, unresectable thymic carcinoma (UTC). **POSOLOGY:** LENVIMA treatment should be initiated and supervised by a health care professional experienced in the use of anticancer therapies. If a patient misses a dose, and it cannot be taken within 12 hours, then that dose should be skipped and the next dose should be taken at the usual time of administration.	**EISAI (MALAYSIA) SDN. BHD.** Unit 701D, Level 7, Tower D, Uptown 5, No.5, Jalan SS21/39, Damansara Uptown, 47400 Petaling Jaya Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
	Lenvima 10mg Hard Capsules [Lenvatinib mesilate 12.25mg (equivalent to 10mg lenvatinib)	Treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs. Optimal medical management (i.e. treatment or therapy) for nausea, vomiting, and diarrhea should be initiated prior to any lenvatinib therapy interruption or dose reduction; however, gastrointestinal toxicity should be actively treated in order to reduce the risk of development of renal impairment or failure. **Posology** <u>Differentiated Thyroid Cancer (DTC) & Unresectable Thymic Carcinoma (UTC)</u> The recommended daily dose of lenvatinib is 24 mg (two 10 mg capsules and one 4 mg capsule) once daily. The daily dose is to be modified as needed according to the dose/toxicity management plan. <u>Renal Cell Carcinoma (RCC)</u> <u>Lenvatinib in combination with pembrolizumab</u> Initial dosing regimen The recommended starting daily dose of lenvatinib is 20mg (two 10 mg capsules) once daily in combination with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks. Refer to the pembrolizumab prescribing information for other pembrolizumab dosing	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		information. Lenvatinib in combination with everolimus Initial dosing regimen The recommended daily dose of lenvatinib is 18 mg (one 10 mg capsule and two 4 mg capsules) once daily in combination with 5 mg of everolimus once daily. The daily doses of lenvatinib and, if necessary, everolimus are to be modified as needed according to the dose/toxicity management plan. Hepatocellular Carcinoma (HCC) The recommended daily dose of lenvatinib is 8 mg (two 4 mg capsules) once daily for patients with a body weight of < 60 kg and 12 mg (three 4 mg capsules) once daily for patients with a body weight of ≥ 60 kg. Dose adjustments are based only on toxicities observed and not on body weight changes during treatment. The daily dose is to be modified, as needed, according to the dose/toxicity management plan. Endometrial Carcinoma (EC) The recommended dosage of lenvatinib is 20 mg orally once daily, in combination with pembrolizumab either 200 mg every 3 weeks or 400mg every 6 weeks, administered as an intravenous infusion over 30 minutes, until unacceptable toxicity or disease progression. Refer to the pembrolizumab prescribing information for additional dosing information.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Monitoring, dose modification and discontinuation Management of adverse reactions may require dose interruption, adjustment, or discontinuation of lenvatinib therapy or the combination therapy. Mild to moderate adverse reactions (e.g., Grade 1 or 2) generally do not warrant interruption of lenvatinib or of the combination, unless intolerable to the patient despite optimal management. Severe (e.g., Grade 3) or intolerable adverse reactions require interruption of lenvatinib or of the combination of medicines until improvement of the reaction to Grade 0-1 or baseline. Treatment should be discontinued in case of life-threatening reactions (e.g., Grade 4) with the exception of laboratory abnormality judged to be non-life-threatening, in which case they should be managed as severe reactions (e.g., Grade 3). Dose adjustment and discontinuations for DTC and UTC For lenvatinib related toxicities (see Table 1), upon resolution/improvement of an adverse reaction to Grade 0-1 or baseline, treatment should be resumed at a reduced dose of lenvatinib as suggested in Table 2. Dose adjustment and discontinuations for RCC In combination with pembrolizumab For lenvatinib-related toxicities, upon resolution/improvement of an adverse reaction, treatment should be resumed at a reduced dose as suggested in Table 3. When used in combination with pembrolizumab, one or both medicines should be interrupted as	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		appropriate. Lenvatinib should be withheld, dose reduced, or discontinued as appropriate. Withhold or discontinue pembrolizumab in accordance with the instructions in the prescribing information for pembrolizumab. No dose reductions are recommended for pembrolizumab. <u>In combination with everolimus</u> For toxicities thought to be related to everolimus, treatment should be interrupted, reduced to alternate day dosing, or discontinued (see the everolimus prescribing information for advice on specific adverse reactions). For toxicities thought to be related to both lenvatinib and everolimus, lenvatinib should be reduced (see Table 3) prior to reducing everolimus. Dose adjustment and Discontinuation for HCC Management of some adverse reactions may require dose interruption, adjustment, or discontinuation of lenvatinib therapy. Mild to moderate adverse reactions (e.g., Grade 1 or 2) generally do not warrant interruption of lenvatinib, unless intolerable to the patient despite optimal management. Details for monitoring, dose adjustment and discontinuation are provided in Table 4.	

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
Dose adjustment and Discontinuation for EC

For lenvatinib-related toxicities see Table 1. When administering lenvatinib in combination with pembrolizumab, interrupt, dose reduce, or discontinue lenvatinib as appropriate (see table 5). Withhold or discontinue pembrolizumab in accordance with the instructions in the prescribing information for pembrolizumab. No dose reductions are recommended for pembrolizumab.

Table 1 Adverse reactions requiring dose modification of lenvatinib
<table>
<tr><th>Adverse reaction</th><th>Severity</th><th>Action</th><th>Dose reduce and resume lenvatinib</th></tr>
<tr><td rowspan="2">Hypertension</td><td>Grade 3 (despite optimal antihypertensive therapy)</td><td>Interrupt</td><td>Resolves to Grade 0, 1 or 2.</td></tr>
<tr><td>Grade 4</td><td>Discontinue</td><td>Do not resume</td></tr>
<tr><td>Proteinuria</td><td>≥ 2 gm / 24 hours</td><td>Interrupt</td><td>Resolves to less than 2 gm / 24 hours.</td></tr>
<tr><td>Nephrotic syndrome</td><td>-------</td><td>Discontinue</td><td>Do not resume</td></tr>
<tr><td>Renal impairment or</td><td>Grade 3</td><td>Interrupt</td><td>Resolves to Grade 0-1 or</td></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication				Product Registration Holder (PRH)
		failure			baseline.	
			Grade 4*	Discontinue	Do not resume	
		Cardiac dysfunction	Grade 3	Interrupt	Resolves to Grade 0-1 or baseline.	
			Grade 4	Discontinue	Do not resume	
		PRES/RPLS	Any grade	Interrupt	Consider resuming at reduced dose if resolves to Grade 0-1.	
		Hepatotoxicity	Grade 3	Interrupt	Resolves to Grade 0-1 or baseline.	
			Grade 4*	Discontinue	Do not resume	
		Arterial thromboembolisms	Any grade	Discontinue	Do not resume	
		Haemorrhage	Grade 3	Interrupt	Resolves to Grade 0-1	
			Grade 4	Discontinue	Do not resume	

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No.	Product [Active Ingredient]	Additional Indication				Product Registration Holder (PRH)
		GI perforation or fistula	Grade 3	Interrupt	Resolves to Grade 0-1 or baseline.	
			Grade 4	Discontinue	Do not resume	
		Non-GI fistula	Grade 4	Discontinue	Do not resume	
		QT interval prolongation	> 500 ms	Interrupt	Resolves to < 480 ms or baseline	
		Diarrhea	Grade 3	Interrupt	Resolves to Grade 0-1 or baseline.	
			Grade 4 (despite medical management)	Discontinue	Do not resume	
		*Grade 4 laboratory abnormalities judged to be non-life-threatening, may be managed as severe reactions (e.g., Grade 3)				

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

Table 2 Dose modifications from recommended lenvatinib daily dose in DTC[a] and UTC[b]

<table>
<tr><th>Dose level</th><th>Daily dose</th><th>Number of capsules</th></tr>
<tr><td>Recommended daily dose</td><td>24 mg orally once daily</td><td>Two 10 mg capsules plus one 4 mg capsule</td></tr>
<tr><td>First dose reduction</td><td>20 mg orally once daily</td><td>Two 10 mg capsules</td></tr>
<tr><td>Second dose reduction</td><td>14 mg orally once daily</td><td>One 10 mg capsule plus one 4 mg capsule</td></tr>
<tr><td>Third dose reduction</td><td>10 mg orally once dailya</td><td>One 10 mg capsule</td></tr>
<tr><td colspan="3">[a]: Further dose reductions should be considered on an individual patient basis as limited data are available for doses below 10 mg.

[b]: In cases where administration is to be continued at a reduced dose, it should be reduced to 20 mg, 14 mg, 10 mg, 8 mg or 4 mg once a day.</td></tr>
</table>

</td><td></td></tr>
</table>

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

Table 3 Dose modifications from recommended lenvatinib daily dose in RCC[a]

<table>
<tr><th>Dose level</th><th>Daily dose</th><th>Number of capsules</th></tr>
<tr><td>Recommended daily dose</td><td>18 mg orally once daily (in combination with everolimus)
or
20 mg orally once daily
(in combination with pembrolizumab)</td><td>One 10 mg capsule plus two 4 mg capsules

Two 10 mg capsules</td></tr>
<tr><td>First dose reduction</td><td>14 mg orally once daily</td><td>One 10 mg capsule plus one 4 mg capsule</td></tr>
<tr><td>Second dose reduction</td><td>10 mg orally once daily</td><td>One 10 mg capsule</td></tr>
<tr><td>Third dose reduction</td><td>8 mg orally once daily</td><td>Two 4 mg capsules</td></tr>
<tr><td colspan="3">[a] Limited data are available for doses below 8 mg</td></tr>
</table>

</td><td></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></td><td></td><td>
Table 4 Dose modifications from recommended lenvatinib daily dose in HCC
<table>
<tr><td colspan="2">Starting Dose</td><td>≥60 kg BW
12 mg (three 4 mg capsules orally once daily)</td><td><60 kg BW
8mg (two 4 mg capsules orally once daily)</td></tr>
<tr><td colspan="4">Persistent and Intolerable Grade 2 or Grade 3 Toxicities [a]</td></tr>
<tr><td>Adverse Reaction</td><td>Modification</td><td>Adjusted Dose[b]
(≥60 kg BW)</td><td>Adjusted Dose[b]
(<60 kg BW)</td></tr>
<tr><td>First occurrence [c]</td><td>Interrupt until resolved to Grade 0-1 or baseline [d]</td><td>8 mg
(two 4 mg capsules)
orally once daily</td><td>4 mg
(one 4 mg capsule)
orally once daily</td></tr>
<tr><td>Second occurrence
(same reaction or new reaction)</td><td>Interrupt until resolved to Grade 0-1 or baseline [d]</td><td>4 mg
(one 4 mg capsule)
orally once daily</td><td>4 mg
(one 4 mg capsule)
orally every other day</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Third occurrence

(same reaction or new reaction)</td><td>Interrupt until resolved to Grade 0-1 or baseline [d]</td><td>4 mg

(one 4 mg capsule) orally every other day</td><td>Discontinue</td></tr>
<tr><td colspan="4">Life-threatening toxicities (Grade 4): Discontinue[e]</td></tr>
<tr><td colspan="4">a. Initiate medical management for nausea, vomiting, or diarrhea prior to interruption or dose reduction.

b. Reduce dose in succession based on the previous dose level (12 mg, 8 mg, 4 mg or 4 mg every other day).

c. Haematologic toxicity or proteinuria-no dose adjustment required for first occurrence.

d. For haematologic toxicity, dosing can restart when resolved to Grade 2; proteinuria, resume when resolves

to less than 2g/24 hours

e. Excluding laboratory abnormalities judged to be nonlife-threatening, which should be managed as Grade 3.</td></tr>
</table>
</td><td></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></td><td></td><td>
Table 5 Dose modifications from recommended lenvatinib daily dose in EC
<table>
<tr><td colspan="2">Starting Dose

in combination with pembrolizumab</td><td>20 mg orally once daily

(two 10 mg capsules)</td></tr>
<tr><td colspan="3">Persistent and Intolerable Grade 2 or Grade 3 Toxicities</td></tr>
<tr><td>Adverse Reaction</td><td>Modification</td><td>Adjusted Dose</td></tr>
<tr><td>First occurrence</td><td>Interrupt until resolved to Grade 0-1 or baseline</td><td>14 mg orally once daily

(one 10 mg capsule + one 4 mg capsule)</td></tr>
<tr><td>Second occurrence

(same reaction or new reaction)</td><td>Interrupt until resolved to Grade 0-1 or baseline</td><td>10 mg orally once daily

(one 10 mg capsule)</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Third occurrence

(same reaction or new reaction)</td><td>Interrupt until resolved to Grade 0-1 or baseline</td><td>8 mg orally once daily

(two 4 mg capsules)</td></tr>
<tr><td colspan="3">Life-threatening toxicities (Grade 4): Discontinue[b]</td></tr>
<tr><td colspan="3">a. Limited data are available for doses below 8 mg.

b. Treatment should be discontinued in case of life-threatening reactions (e.g., Grade 4) with the exception

of laboratory abnormalities judged to be non-life-threatening, in which case they should be managed as

severe reactions (e.g., Grade 3).</td></tr>
</table>

Special populations

DTC:

Patients of age ≥75 years, of Asian race, with comorbidities (such as hypertension, and</td><td></td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		hepatic or renal impairment), or body weight below 60 kg appear to have reduced tolerability to lenvatinib. All patients other than those with severe hepatic or renal impairment (see below) should initiate treatment at the recommended 24 mg dose, following which the dose should be further adjusted on the basis of individual tolerability. UTC: The efficacy and safety of lenvatinib as preoperative adjuvant therapy have not been established. Select patients who are indicated for treatment with lenvatinib after thoroughly understanding the contents of efficacy and safety of the product. RCC: No data for the combination of lenvatinib and everolimus are available for most of the special populations. The following information is derived from the clinical experience on single agent lenvatinib in patients with differentiated thyroid cancer (DTC). All patients other than those with severe hepatic or renal impairment (see below) should initiate treatment at the recommended dose of 20 mg of lenvatinib daily with pembrolizumab or 18 mg of lenvatinib with 5 mg of everolimus taken once daily as indicated, following which the dose should be further adjusted on the basis of individual tolerability.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		HCC: Patients ≥75 years, of white race or female sex or those with worse baseline hepatic impairment (Child-Pugh A score of 6 compared to score of 5) appear to have reduced tolerability to lenvatinib. HCC patients other than those with moderate and severe hepatic impairment or severe renal impairment should initiate treatment at the recommended starting dose of 8 mg (two 4 mg capsules) for body weight < 60 kg and 12 mg (three 4 mg capsules) for body weight ≥ 60 kg, following which the dose should be further adjusted on the basis of individual tolerability. Patients with hypertension Blood pressure should be well controlled prior to treatment with lenvatinib, and should be regularly monitored during treatment. Patients with hepatic impairment <u>DTC, RCC and EC</u> No dose adjustments are required on the basis of hepatic function in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment. The recommended dosage of lenvatinib for patients with severe hepatic impairment (Child-	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Pugh C) is: • DTC: 14 mg taken orally once daily • RCC: 10 mg taken orally once daily • EC: 10 mg taken orally once daily Further dose adjustments may be necessary on the basis of individual tolerability. Limited data are available for the combination of lenvatinib with pembrolizumab or everolimus in patients with hepatic impairment. Please refer to the respective prescribing information for pembrolizumab or everolimus for dosing in patients with hepatic impairment. <u>HCC</u> No dose adjustments are required on the basis of hepatic function in patients with HCC and mild hepatic impairment (Child-Pugh A). There are limited data in patients with HCC and moderate hepatic impairment (Child-Pugh B). On the basis of that data, the recommended starting dose in patients with moderate hepatic impairment (Child-Pugh B) is 8 mg, regardless of body weight. Patients with moderate hepatic impairment may require additional monitoring for adverse reactions requiring dose adjustments. The available data do not allow for a dosing recommendation for patients with HCC and severe hepatic impairment (Child-Pugh C).	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Patients with renal impairment <u>DTC, RCC and EC</u> No dose adjustments are required on the basis of renal function in patients with mild or moderate renal impairment. The recommended dosage of lenvatinib for patients with severe renal impairment (creatinine clearance less than 30 mL/min calculated by Cockcroft-Gault equation using actual body weight) is: • DTC: 14 mg taken orally once daily • RCC: 10 mg taken orally once daily • EC: 10 mg taken orally once daily Further dose adjustments may be necessary on the basis of individual tolerability. Patients with end-stage renal disease have not been studied, therefore the use of lenvatinib in these patients is not recommended. Limited data are available for the combination of lenvatinib with pembrolizumab or everolimus in patients with renal impairment. Please refer to the respective prescribing information for pembrolizumab or everolimus for dosing in patients with renal impairment.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		HCC No dose adjustments are required on the basis of renal function in HCC patients with mild or moderate renal impairment. The available data do not allow for a dosing recommendation for patients with HCC and severe renal impairment. Elderly population No adjustment of starting dose is required on the basis of age. Limited data are available on use in patients aged ≥75 years. Paediatric population The safety and efficacy of lenvatinib in children aged 2 to <18 years have not been established. Lenvatinib should not be used in children younger than 2 years of age because of safety concerns identified in animal studies.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Race No adjustment of starting dose is required on the basis of race. Limited data are available on use in patients from ethnic origins other than Caucasian. <u>Body weight below 60 kg in RCC</u> No adjustment of starting dose is required on the basis of body weight. Limited data are available on treatment with lenvatinib in combination with everolimus in patients with a body weight below 60 kg with RCC. <u>Patients with high ECOG performance status in RCC</u> Patients with an ECOG (Eastern Cooperative Oncology Group) performance status of 2 or higher were excluded from the RCC Study 205. Patients with a KPS (Karnofsky Performance Status) <70 were excluded from Study 307 (CLEAR). Benefit-risk in these patients has not been evaluated. <u>Method of administration</u> Lenvatinib is for oral use. The capsules should be taken at about the same time each day, with or without food. The capsules should be swallowed whole with water. Caregivers	

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		should not open the capsule, in order to avoid repeated exposure to the contents of the capsule. Alternatively, the lenvatinib capsules may be added without breaking or crushing them to a tablespoon of water or apple juice in a small glass to produce a suspension. The capsules must be left in the liquid for at least 10 minutes and stirred for at least 3 minutes to dissolve the capsule shells. The suspension is to be swallowed. After drinking, the same amount of water or apple juice (one tablespoon) must be added to the glass and swirled a few times. The additional liquid must be swallowed.	
3.	Tevimbra 100mg / 10 ml Concentrate for Solution for Infusion [Tislelizumab 100 mg/10 ml]	**INDICATION:** Nasopharyngeal carcinoma (NPC) Tevimbra, in combination with gemcitabine and cisplatin, is indicated for the first-line treatment of adult patients with recurrent, not amenable to curative surgery or radiotherapy, or metastatic NPC. **POSOLOGY:** No change of posology.	**BEONE MEDICINES MALAYSIA SDN. BHD.** Anchor Office 4, Level 4, Uptown 7, Jalan SS21/39, Damansara Utama, 47400 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Darzalex Faspro 1,800 mg solution for injection [Daratumumab 120mg/mL]	**INDICATION:** DARZALEX FASPRO is indicated for the treatment of adult patients with multiple myeloma: • in combination with lenalidomide and dexamethasone - in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan, prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • **in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma.** • in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. • in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. • in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy. • in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.	**JOHNSON & JOHNSON SDN. BHD.** Level 8, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 46150 Petaling Jaya, Selangor.

<table>
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• as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Light chain (AL) amyloidosis
DARZALEX FASPRO is indicated in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic AL amyloidosis.

POSOLOGY:
The DARZALEX FASPRO dosing schedule in Table 5 is for combination therapy with bortezomib, lenalidomide and dexamethasone (3-week cycle regimens) for treatment of newly diagnosed multiple myeloma patients for whom ASCT is not planned as initial therapy or who are ineligible for ASCT. The recommended dose is DARZALEX FASPRO 1800 mg administered subcutaneously, over approximately 3-5 minutes, according to the following dosing schedule:

Table 5: DARZALEX FASPRO dosing schedule in combination with bortezomib, lenalidomide and dexamethasone ([VRd]; 3-week cycle dosing regimen)
<table>
<tr><th>Weeks</th><th>Schedule</th></tr>
<tr><td>Weeks 1 to 6</td><td>weekly (total of 6 doses)</td></tr>
</table>
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<table>
<tr><td>Weeks 7 to 24[a]</td><td>every three weeks (total of 6 doses)</td></tr>
<tr><td>Week 25 onwards until disease progression[b]</td><td>every four weeks</td></tr>
</table>
[a] First dose of the every-3-week dosing schedule is given at week 7.
[b] First dose of the every-4-week dosing schedule is given at week 25.

For dosing instructions of medicinal products administered with DARZALEX FASPRO, see Clinical Studies and manufacturer’s prescribing information.
</td><td></td></tr>
</table>