Maklumat tambahan indikasi
Year 2020
Products Approved For Additional Indication (DCA 343 – 13 February 2020)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Symbicort Turbuhaler 160/4.5 mcg/dose** [Budesonide 160mcg/Formoterol fumarate dihydrate 4.5mcg]	➢ Indication: *Asthma* *Symbicort Turbuhaler is indicated for the treatment of asthma, to achieve overall asthma control, including the relief of symptoms and the reduction of the risk of exacerbations.* ➢ Posology: *Asthma* *Symbicort Turbuhaler can be used according to different treatment approaches:* *A. Symbicort anti-inflammatory reliever therapy (patients with mild disease).* *B. Symbicort anti-inflammatory reliever plus maintenance therapy.* *C. Symbicort maintenance therapy (fixed dose).* *A. Symbicort anti-inflammatory reliever therapy (patients with mild disease)* *Symbicort Turbuhaler 160/4.5 µg/inhalation is taken as needed for the relief of asthma symptoms when they occur. Patients should be advised to always have Symbicort Turbuhaler 160/4.5 µg/inhalation available for relief of symptoms.* *<u>Adults and adolescents (12 years and older)</u>* *Patient should take 1 inhalation of Symbicort Turbuhaler 160/4.5 µg/inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. No more than 6 inhalations should be taken on any single occasion.* *A total daily dose of more than 8 inhalations is normally not needed, however a total daily dose of up to 12 inhalations*	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower No. 10, Jalan PJU 7/6, Mutiara Damansara 47800 Petaling Jaya, Selangor

		can be used temporarily. If the patient experiences a three-day period of deteriorating symptoms after taking additional as needed inhalation, the patient should be reassessed for alternative explanations of persisting symptoms. *Symbicort Turbuhaler 80/4.5 mcg/inhalation should NOT be used as Symbicort Anti-inflammatory Reliever Therapy.* *<u>Children under 12 years</u>* *Symbicort anti-inflammatory reliever therapy is not recommended for children.*	
2.	2.1 **Zerbaxa 1.5g powder for solution for injection** [Ceftolozane sulfate 1147 mg (Ceftolozane 1g) and Tazobactam sodium 537mg (Tazobactam 500mg)]	➢ Indication: *Nosocomial Pneumonia, including Ventilator-associated Pneumonia* *Treatment of nosocomial pneumonia, including ventilator-associated pneumonia, caused by the following susceptible Gram-negative microorganisms: Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Serratia marcescens.* ➢ Posology: ***Recommended Dosage*** **The recommended dosage regimen of ZERBAXA for injection is 3 g (ceftolozane 2 g and tazobactam 1 g) for nosocomial pneumonia administered every 8 hours by intravenous infusion over 1 hour in patients 18 years or older and with normal renal function or mild renal impairment. The duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress as shown in Table 1.** **Table 1: Dosage of ZERBAXA by Infection in Patients with Creatinine Clearance (CrCl) Greater than 50 mL/min** **Infection** | **Dose** | **Frequency** | **Infusion Time (hours)** | **Duration of Treatment**	**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

Nosocomial Pneumonia, including Ventilator-associated Pneumonia	**3 g**	**Every 8 Hours**	**1**	**8-14 days**

Patients with Renal Impairment

Dose adjustment is required for patients whose creatinine clearance is 50 mL/min or less. Renal dose adjustments are listed in Table 2. For patients with changing renal function, monitor CrCl at least daily and adjust the dosage of ZERBAXA accordingly.

Table 2: Recommended Dosage Regimens for ZERBAXA in Patients with Renal Impairment

Estimated CrCl (mL/min)*	Nosocomial Pneumonia, including Ventilator-associated Pneumonia†
30 to 50	1.5 g (1 g and 0.5 g) intravenously every 8 hours
15 to 29	750 mg (500 mg and 250 mg) intravenously every 8 hours
End-stage renal disease (ESRD) on hemodialysis (HD)	A single loading dose of 2.25 g (1.5 g and 0.75 g) followed after 8 hours by a 450 mg (300 mg and 150 mg) maintenance dose administered every 8 hours for the remainder of the treatment period (on hemodialysis days, administer the dose at the earliest possible time following completion of dialysis)

*** CrCl estimated using Cockcroft-Gault formula**
† All doses of ZERBAXA are administered over 1 hour.

Patients with Hepatic impairment

No dose adjustment is necessary in patients with hepatic impairment.

Preparation of Solutions

ZERBAXA does not contain a bacteriostatic preservative. Aseptic technique must be followed in preparing the infusion solution.

Preparation of doses:

Constitute each vial of ZERBAXA with 10 mL of sterile

		water for injection or 0.9% Sodium Chloride for Injection, USP and gently shake to dissolve. The final volume is approximately 11.4 mL per vial. Caution: The constituted solution is not for direct injection. **To prepare the required dose, withdraw the appropriate volume determined from Table 3 from the reconstituted vial(s). Add the withdrawn volume to an infusion bag containing 100 mL of 0.9% Sodium Chloride for Injection, USP or 5% Dextrose Injection, USP.** **Table 3: Preparation of Doses** **ZERBAXA (ceftolozane and tazobactam) Dose** / **Volume to Withdraw from Reconstituted Vial(s)** **3 g (2 g and 1 g)** / **Two vials of 11.4 mL each (entire contents from two vials)** **2.25 g (1.5 g and 0.75 g)** / **11.4 mL from one vial (entire contents) and 5.7 mL from a second vial** **1.5 g (1 g and 0.5 g)** / **11.4 mL (entire contents from one vial)** **750 mg (500 mg and 250 mg)** / **5.7 mL** **450 mg (300 mg and 150 mg)** / **3.5 mL** **375 mg (250 mg and 125 mg)** / **2.9 mL** **150 mg (100 mg and 50 mg)** / **1.2 mL** **Inspect drug products visually for particulate matter and discoloration prior to use. ZERBAXA infusions range from clear, colorless solutions to solutions that are clear and slightly yellow. Variations in color within this range do not affect the potency of the product.**	
3.	**3.1 Pomalyst® Capsules 1mg** [Pomalidomide 1mg] **3.2 Pomalyst® Capsules 2mg** [Pomalidomide 2mg] **3.3 Pomalyst® Capsules 3mg** [Pomalidomide 3mg]	➢ Indication: *Pomalyst® in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior treatment regimen including lenalidomide.*	**CELGENE SDN. BHD.** Lot 6.05, Level 6, KPMG Tower 8 First Avenue, Bandar Utama 47800 Petaling Jaya, Selangor

3.4 Pomalyst® Capsules 4mg
[Pomalidomide 4mg]

- Posology:

Treatment must be initiated and monitored under the supervision of physicians experienced in the management of multiple myeloma.

Dosing is continued or modified based upon clinical and laboratory findings (see section 4.4).

<u>Posology</u>

- *Pomalidomide in combination with bortezomib and dexamethasone*
  The recommended starting dose of Pomalyst® is 4 mg orally once daily on Days 1 to 14 of repeated 21- day cycles.

  Pomalidomide is administered in combination with bortezomib and dexamethasone, as shown in Table 1. The recommended starting dose of bortezomib is 1.3 mg/m² intravenous or subcutaneous once daily, on the days shown in Table 1. The recommended dose of dexamethasone is 20 mg orally once daily, on the days shown in Table 1.

  Treatment with pomalidomide combined with bortezomib and dexamethasone should be given until disease progression or until unacceptable toxicity occurs.

Table 1. Recommended dosing scheme for Pomalyst® in combination with bortezomib and dexamethasone

Cycle 1-8	Day (of 21-day cycle)																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Pomalidomide (4 mg)	•	•	•	•	•	•	•	•	•	•	•	•	•	•							
Bortezomib (1.3 mg/m^2)	•			•				•			•										
Dexamethasone (20 mg) *	•	•		•	•			•	•		•	•									

Cycle 9 onwards	Day (of 21-day cycle)																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Pomalidomide (4 mg)	•	•	•	•	•	•	•	•	•	•	•	•	•	•							
Bortezomib (1.3 mg/m^2)	•							•													
Dexamethasone (20 mg) *	•	•						•	•												

* For patients > 75 years of age, see Special populations.

Pomalidomide dose modification or interruption
To initiate a new cycle of pomalidomide, the neutrophil count must be ≥ 1 x 10^9/l and the platelet count must be ≥ 50 x 10^9/l.

Instructions on dose interruptions or reductions for pomalidomide related adverse reactions are outlined in the Table 2 and dose levels are defined in Table 3 below:

Table 2. Pomalidomide dose modification instructions∞

Toxicity	Dose modification
Neutropenia* • ANC** < 0.5 x 10^9/l or Febrile neutropenia (fever ≥38.5°C and ANC ,1 x 10^9/l)	Interrupt pomalidomide treatment for remainder of cycle. Follow CBC*** weekly.
• ANC return to ≥1 x 10^9/l	Resume pomalidomide treatment at 3mg daily.
• For each subsequent drop < 0.5 x 10^9/l	Interrupt pomalidomide treatment
• ANC return to ≥1 x 10^9/l	Resume pomalidomide treatment at 1 mg less than the previous dose.
Thrombocytopenia • Platelet count <25 x 10^9/l	Interrupt pomalidomide treatment for remainder of cycle. Follow CBC*** weekly.
• Platelet count ≥50 x 10^9/l	Resume pomalidomide treatment at 3 mg daily
• For each subsequent drop <25 x 10^9/l	Interrupt pomalidomide treatment
• Platelet count return to	Resume pomalidomide

≥50 x 10^9/l	treatment at 1 mg less than the previous dose
<u>Rash</u> Rash = Grade 2 -3	Consider dose interruption or discontinuation of pomalidomide treatment.
Rash = Grade 4 or blistering (including angioedema, exfoliative or bullous rash or if Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) is suspected)	Permanently discontinue treatment (see section 4.4).
Other Other ≥ Grade 3 pomalidomide-related adverse events	Interrupt pomalidomide treatment for remainder of cycle. Resume at one dose level lower than previous dose at next cycle (adverse event must be resolved or improved to ≤ Grade 2 before restarting dosing).

∞ Dose modification instructions in this table are applicable to pomalidomide in combination with bortezomib and dexamethasone and to pomalidomide in combination with dexamethasone.
*In case of neutropenia, the physician should consider the use of growth factors.
**ANC – Absolute Neutrophil Count; ***CBC – Complete Blood Count.

Table 3. Pomalidomide dose reduction∞

Dose level	Oral pomalidomide dose
Starting dose 4 mg	Starting dose 4 mg
Dose level -1 3 mg	Dose level -1 3 mg
Dose level -2 2 mg	Dose level -2 2 mg
Dose level -3 1 mg	Dose level -3 1 mg

∞Dose reduction in this table is applicable to pomalidomide in combination with bortezomib and dexamethasone and to pomalidomide in combination with dexamethasone.

If adverse reactions occur after dose reductions to 1 mg, then the medicinal product should be discontinued.

<u>Strong CYP1A2 inhibitors</u>
If strong inhibitors of CYP1A2 (e.g. ciprofloxacin,

enoxacin and fluvoxamine) are co-administered with pomalidomide, reduce the dose of pomalidomide by 50% (see section 4.5 and 5.2).
Bortezomib dose modification or interruption
For instructions on dose interruptions or reductions for bortezomib related adverse reactions, physicians should refer to bortezomib Package Insert.

Dexamethasone dose modification or interruption
Instructions on dose interruptions or reductions for low-dose dexamethasone related adverse reactions are outlined in Tables 4 and 5 below. However, dose interruption or resumption decisions are at the physician's discretion per Package Insert.

Table 4. Dexamethasone dose modification instructions

Toxicity	Dose modification
Dyspepsia = Grade 1-2	Maintain dose and treat with histamine (H_2) blockers or equivalent. Decrease by one dose level if symptoms persist.
Dyspepsia ≥ Grade 3	Interrupt dose until symptoms are controlled. Add H_2 blocker or equivalent and decrease one dose level when dose restarted.
Oedema ≥ Grade 3	Use diuretics as needed and decrease dose by one dose level.
Confusion or mood alteration ≥ Grade 2	Interrupt dose until symptoms resolve. Resume at one dose level lower than previous dose.
Muscle weakness ≥ Grade 2	Interrupt dose until muscle weakness ≤ Grade 1. Resume at one dose level lower than previous dose.
Hyperglycaemia ≥ Grade 3	Decrease dose by one dose level. Treat with insulin or oral hypoglycaemic agents as needed
Acute pancreatitis	Discontinue patient from dexamethasone treatment regimen.
Other ≥ Grade 3 dexamethasone-related adverse events	Stop dexamethasone dosing until adverse event resolves to ≤ Grade 2. Resume at one dose level lower than previous dose.

If recovery from toxicities is prolonged beyond 14 days, then the dose of dexamethasone will be resumed at one

dose level lower than the previous dose.

Table 5. Dexamethasone dose reduction

Dose Level	≤ 75 years old Dose (Cycle 1-8: Days 1, 2, 4, 5, 8, 9, 11, 12 of a 21-day cycle Cycle ≥ 9: Days 1, 2, 8, 9 of a 21-day cycle)	> 75 years old Dose (Cycle 1-8: Days 1, 2, 4, 5, 8, 9, 11, 12 of a 21-day cycle Cycle ≥ 9: Days 1, 2, 8, 9 of a 21-day cycle)
Starting dose	20 mg	10 mg
Dose Level -1	12 mg	6 mg
Dose Level -2	8 mg	4 mg

Dexamethasone should be discontinued if the patient is unable to tolerate 8 mg if ≤ 75 years old or 4 mg if > 75 years old.

In case of permanent discontinuation of any component of the treatment regimen, continuation of the remaining medicinal products is at the physician's discretion.

- *Pomalidomide in combination with dexamethasone*

The recommended starting dose of Pomalyst® is 4 mg orally once daily on Days 1 to 21 of repeated 28-day cycles.

The recommended dose of dexamethasone is 40 mg orally once daily on Days 1, 8, 15 and 22 of each 28-day treatment cycle.

Treatment with pomalidomide combined with dexamethasone should be given until disease progression or until unacceptable toxicity occurs.

Pomalidomide dose modification or interruption
Instructions for dose interruptions or reductions for pomalidomide related adverse reactions are outlined in

Table 2 and 3.

Dexamethasone dose modification or interruption Instructions for dose modification for dexamethasone related adverse reactions are outlined in Table 4. Instructions for dose reduction for dexamethasone related adverse reactions are outlined in Table 6 below. However, dose interruption / resumption decisions are at physician's discretion per the current Package Insert.

Table 6. Dexamethasone dose reduction

Dose Level	≤ 75 years old Days 1, 8, 15 and 22 of each 28-day treatment cycle	> 75 years old Days 1, 8, 15 and 22 of each 28-day treatment cycle
Starting dose	40 mg	20 mg
Dose Level -1	20 mg	12 mg
Dose Level -2	10 mg	8 mg

Dexamethasone should be discontinued if the patient is unable to tolerate 10 mg if ≤ 75 years old or 8 mg if > 75 years old.

<u>Special populations</u>
Elderly

- *Pomalidomide in combination with bortezomib and dexamethasone*
  No dose adjustment is required for pomalidomide.

  For information on bortezomib given in combination with Pomalyst®, refer to the respective current Package Insert.

  For patients >75 years of age, the starting dose of dexamethasone is:
- *For Cycles 1 to 8: 10 mg once daily on Days 1, 2, 4, 5, 8, 9, 11 and 12 of each 21-day cycle*
- *For Cycles 9 and onwards: 10 mg once daily on Days 1, 2, 8 and 9 of each 21-day cycle.*

<u>Renal impairment</u>
No dose adjustment of pomalidomide is required for patients with renal impairment. On haemodialysis days, patients should take their pomalidomide dose following haemodialysis.

<u>Hepatic impairment</u>
Patients with serum total bilirubin > 1.5 x ULN (upper limit of normal range) were excluded from clinical studies. Hepatic impairment has a modest effect on the pharmacokinetics of pomalidomide (see section 5.2). No adjustment of the starting dose of pomalidomide is required for patients with hepatic impairment as defined by the Child-Pugh criteria. However, patients with hepatic impairment should be carefully monitored for adverse reactions and dose reduction or interruption of pomalidomide should be used as needed.

Paediatric population
There is no relevant use of Pomalyst® in children aged 0-17 years for the indication of multiple myeloma.

<u>Method of administration</u>
Oral use.
Pomalyst® should be taken orally at the same time each day. The capsules should not be opened, broken or chewed (see section 6.6). This medicinal product should be swallowed whole, preferably with water, with or without food. If the patient forgets to take a dose of Pomalyst® on one day, then the patient should take the normal prescribed dose as scheduled on the next day. Patients should not adjust the dose to make up for a missing dose on previous days.

It is recommended to press only on one end of the capsule to remove it from the blister thereby reducing the risk of capsule deformation or breakage.

For information on other medicinal products given in

		combination with Pomalyst®, refer to the respective current Package Insert.	
4.	4.1 **KEYTRUDA 100MG SOLUTION FOR INFUSION** [Pembrolizumab 100mg]	➢ Indication: <u>*Renal Cell Carcinoma*</u> *KEYTRUDA, in combination with axitinib is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).* ➢ Posology: ***General*** ***Patient Selection for Non-Small Cell Lung Carcinoma or Urothelial Carcinoma*** *Select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression in:* • *advanced NSCLC* • *locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy* ***Recommended Dosing*** *KEYTRUDA is administered as an intravenous infusion over 30 minutes every 3 weeks.* *The recommended dose of KEYTRUDA is:* • *200 mg for head and neck cancer, urothelial carcinoma, classical Hodgkin Lymphoma or previously untreated NSCLC as monotherapy.* • *200mg for NSCLC **or RCC** in combination therapy* • *2 mg/kg for melanoma or previously treated NSCLC as monotherapy.* *For use in combination, see the prescribing information for the concomitant therapies. When administering KEYTRUDA as part of a combination with intravenous chemotherapy, KEYTRUDA should be administered first.*	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** B-22-1 & B-22-2, The Ascent Paradigm No. 1 Jalan SS 7/26A, Kelana Jaya 47301 Petaling Jaya, Selangor

For RCC patients treated with KEYTRUDA in combination with axitinib, see the prescribing information regarding dosing of axitinib. When used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer [see Clinical Studies (IIId)].

Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e., an initial transient increase in tumor size or small new lesions within the first few months followed by tumor shrinkage) have been observed. Clinically stable patients with initial evidence of disease progression should remain on treatment until disease progression is confirmed.

Dose modifications

Table 14: Recommended Dose Modifications [see Precautions (VIII)]

Adverse reactions	***Severity***	***Dose modification***
Immune-mediated pneumonitis	*Moderate (Grade 2)*	*Withhold until adverse reactions recover to Grades 0-1**
	Severe or life-threatening (Grades 3 or 4) or recurrent moderate (Grade 2)	*Permanently discontinue*
Immune-mediated colitis	*Moderate or severe (Grades 2 or 3)*	*Withhold until adverse reactions recover to Grades 0-1**
	Life-threatening (Grade 4) or recurrent severe (Grade 3)	*Permanently discontinue*
Immune-	*Moderate*	*Withhold until*

mediated nephritis	*(Grade 2)*	*adverse reactions recover to Grades 0-1**
	Severe or life-threatening (Grade 3 or 4)	*Permanently discontinue*
Immune-mediated endocrinopathies	*Severe or life-threatening (Grades 3 or 4)*	*Withhold until adverse reactions recover to Grades 0-1** *For patients with severe (Grade 3) or life-threatening (Grade 4) endocrinopathy that improves to Grade 2 or lower and is controlled with hormone replacement, continuation of KEYTRUDA may be considered.*
Immune-mediated hepatitis ***For liver enzyme elevations in RCC patients treated with combination therapy, see dosing guidelines following this table.***	*Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3 to 5 times upper limit of normal (ULN) or total bilirubin >1.5 to 3 times ULN*	*Withhold until adverse reactions recover to Grades 0-1**
	AST or ALT >5 times ULN or total bilirubin >3 times ULN	*Permanently discontinue*

	For patients with liver metastases who begin treatment with moderate (Grade 2) elevation of AST or ALT, if AST or ALT increases ≥50% relative to baseline and lasts ≥1 week	*Permanently discontinue*
Immune-mediated skin reactions or Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)	*Severe skin reactions (Grade 3) or suspected SJS or TEN*	*Withhold until adverse reactions recover to Grades 0-1**
	Severe skin reactions (Grade 4) or confirmed SJS or TEN	*Permanently discontinue*
Other immune-mediated adverse reactions	*Based on severity and type of reaction (Grade 2 or Grade 3)*	*Withhold until adverse reactions recover to Grades 0-1**
	Severe or life-threatening (Grades 3 or 4) myocarditis, encephalitis, or Guillain-Barré syndrome	*Permanently discontinue*
	Life-threatening (Grade 4) or recurrent severe (Grade 3)	*Permanently discontinue*
Infusion-related reactions	*Severe or life-threatening (Grades 3 or 4)*	*Permanently discontinue*

		Note: toxicity grades are in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0 (NCI CTCAE v.4) ** If corticosteroid dosing cannot be reduced to ≤10 mg prednisone or equivalent per day within 12 weeks or a treatment-related toxicity does not resolve* *to Grades 0-1 within 12 weeks after last dose of KEYTRUDA, then KEYTRUDA should be permanently discontinued.* *In patients with cHL with Grade 4 hematological toxicity, KEYTRUDA should be withheld until adverse reactions recover to Grades 0-1.* ***In patients with RCC being treated with KEYTRUDA in combination with axitinib:*** • ***If ALT or AST ≥3 times ULN but <10 times ULN without concurrent total bilirubin ≥2 times ULN, withhold both KEYTRUDA and axitinib until these adverse reactions recover to Grades 0–1. Consider corticosteroid therapy. Consider rechallenge with a single drug or sequential rechallenge with both drugs after recovery. If rechallenging with axitinib, consider dose reduction as per the axitinib prescribing information.*** • ***If ALT or AST ≥10 times ULN or >3 times ULN with concurrent total bilirubin ≥2 times ULN, permanently discontinue both KEYTRUDA and axitinib and consider corticosteroid therapy.***	
5.	5.1 **DARZALEX™ 20MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION** [Daratumumab 20 mg/ml]	➢ Indication: *Darzalex is indicated in combination with lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.* ➢ Posology: *Darzalex should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions (IRRs) if they occur.*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya Selangor

Pre- and post-infusion medications should be administered.

<u>Dosage – Adults (≥18 years)</u>
Recommended dose

The Darzalex dosing schedule in Table 1 is for combination therapy with 4-week cycle regimens (e.g. lenalidomide) and for monotherapy as follows:

- ***combination therapy with lenalidomide and low-dose dexamethasone for patients with newly diagnosed multiple myeloma ineligible for autologous stem cell transplant (ASCT)***
- *combination therapy with lenalidomide and low-dose dexamethasone for patients with relapsed/refractory multiple myeloma*
- *monotherapy for patients with relapsed/refractory multiple myeloma*

The recommended dose is Darzalex 16 mg/kg body weight administered as an intravenous infusion according to the following dosing schedule.

Table 1: Darzalex dosing schedule in combination with lenalidomide (4-week cycle dosing regimens) and low-dose dexamethasone and for monotherapy

Weeks	**Schedule**
Weeks 1 to 8	weekly (total of 8 doses)
Weeks 9 to 24[a]	every two weeks (total of 8 doses)
Week 25 onwards until disease progression[b]	every four weeks

[a] First dose of the every-2-week dosing schedule is given at Week 9
[b] First dose of the every-4-week dosing schedule is given at Week 25

6.	6.1 **SIMPONI IV 12.5MG/1ML CONCENTRATE FOR SOLUTION FOR INFUSION** [Golimumab 12.5mg/ 1ml]	➢ Indication: *<u>Rheumatoid arthritis (RA):</u>* *SIMPONI, by intravenous (IV) administration, in combination with MTX, is indicated for:* • *the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate.* *SIMPONI, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X ray and to improve physical function.* *<u>Ankylosing spondylitis (AS):</u>* *SIMPONI® by intravenous (IV) administration is indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to conventional therapies.* *<u>Psoriatic arthritis (PsA):</u>* *SIMPONI, by intravenous (IV) administration, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate*.	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya Selangor
7.	7.1 **Imbruvica 140mg Capsules** [Ibrutinib 140mg]	➢ Indication: *IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.* ➢ Posology: *Chronic graft versus host disease (cGVHD)* *The recommended dose of IMBRUVICA for cGVHD is 420 mg (three capsules) orally once daily until cGVHD progression, recurrence of an underlying malignancy, or unacceptable toxicity. When a patient no longer requires therapy for the treatment of cGVHD, IMBRUVICA should be discontinued considering the medical assessment of the*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor

individual patient.

dan menambah 'cGVHD' ke dalam jadual di bawah:

Recommended dose modifications are described below:

Toxicity occurrence	*MCL dose modification after recovery*	*CLL/**cGVHD** dose modification after recovery*
First	*restart at 560 mg daily*	*restart at 420 mg daily*
Second	*restart at 420 mg daily*	*restart at 280 mg daily*
Third	*restart at 280 mg daily*	*restart at 140 mg daily*
Fourth	*discontinue IMBRUVICA*	*discontinue IMBRUVICA*