Maklumat tambahan indikasi
Year 2021
Products Approved For Additional Indication (DCA 352 – 8 January 2021)

	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Kyprolis (carfilzomib) powder for solution for infusion 60mg/vial** [Carfilzomib 60mg]	➢ Posology: *Kyprolis in Combination with Dexamethasone* *Once weekly 20/70 mg/m^2 regimen by 30-minute infusion* *Kyprolis is administered intravenously as a 30-minute infusion once weekly for three weeks followed by a 13-day rest period as shown in Table 1. Each 28-day period is considered one treatment cycle. Administer Kyprolis at a starting dose of 20 mg/m^2 in Cycle 1 on Day 1. If tolerated, escalate the dose to 70 mg/m^2 on Day 8 of Cycle 1. Dexamethasone 40 mg is taken by mouth or intravenously on Days 1, 8, and 15 of all cycles and on Day 22 of Cycles 1 to 9. Administer dexamethasone 30 minutes to 4 hours before Kyprolis. Treatment may be continued until disease progression or unacceptable toxicity occurs.* *Table 1: Kyprolis Once Weekly (30-Minute Infusion) in Combination with Dexamethasone*	**AMGEN BIOPHARMACEUTICALS MALAYSIA SDN. BHD.** Suite 9.01, Level 9, Menara Summit Persiaran Kewajipan USJ 1, UEP, 47600, Subang Jaya, Selangor

		<table><tr><th></th><th colspan="12">Cycle 1</th></tr><tr><th></th><th colspan="3">Week 1</th><th colspan="3">Week 2</th><th colspan="3">Week 3</th><th colspan="3">Week 4</th></tr><tr><th></th><th>Day 1</th><th>Day 2</th><th>Days 3–7</th><th>Day 8</th><th>Day 9</th><th>Days 10–14</th><th>Day 15</th><th>Day 16</th><th>Days 17–21</th><th>Day 22</th><th>Day 23</th><th>Days 24-28</th></tr><tr><td>Kyprolis (mg/m²)</td><td>20</td><td>-</td><td>-</td><td>70</td><td>-</td><td>-</td><td>70</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr><tr><td>Dexamethasone (mg)</td><td>40</td><td>-</td><td>-</td><td>40</td><td>-</td><td>-</td><td>40</td><td>-</td><td>-</td><td>40</td><td>-</td><td>-</td></tr></table><table><tr><th></th><th colspan="12">Cycles 2 to 9</th></tr><tr><th></th><th colspan="3">Week 1</th><th colspan="3">Week 2</th><th colspan="3">Week 3</th><th colspan="3">Week 4</th></tr><tr><th></th><th>Day 1</th><th>Day 2</th><th>Days 3–7</th><th>Day 8</th><th>Day 9</th><th>Days 10–14</th><th>Day 15</th><th>Day 16</th><th>Days 17–21</th><th>Day 22</th><th>Day 23</th><th>Days 24-28</th></tr><tr><td>Kyprolis (mg/m²)</td><td>70</td><td>-</td><td>-</td><td>70</td><td>-</td><td>-</td><td>70</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr><tr><td>Dexamethasone (mg)</td><td>40</td><td>-</td><td>-</td><td>40</td><td>-</td><td>-</td><td>40</td><td>-</td><td>-</td><td>40</td><td></td><td>-</td></tr></table><table><tr><th></th><th colspan="12">Cycles 10 and later</th></tr><tr><th></th><th colspan="3">Week 1</th><th colspan="3">Week 2</th><th colspan="3">Week 3</th><th colspan="3">Week 4</th></tr><tr><th></th><th>Day 1</th><th>Day 2</th><th>Days 3–7</th><th>Day 8</th><th>Day 9</th><th>Days 10–14</th><th>Day 15</th><th>Day 16</th><th>Days 17–21</th><th>Day 22</th><th>Day 23</th><th>Days 24-28</th></tr><tr><td>Kyprolis (mg/m²)</td><td>70</td><td>-</td><td>-</td><td>70</td><td>-</td><td>-</td><td>70</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr><tr><td>Dexamethasone (mg)</td><td>40</td><td>-</td><td>-</td><td>40</td><td>-</td><td>-</td><td>40</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr></table>	
2.	2.1 **Forxiga 5mg Film-Coated Tablet** [Dapagliflozin 5mg] 2.2 **Forxiga 10mg Film-Coated Tablet** [Dapagliflozin 10mg]	➢ *Indication:* *<u>Heart failure</u>* *Forxiga is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.* ➢ *Posology:* *<u>Heart failure</u>* *The recommended dose is 10 mg dapagliflozin once daily.* *In the DAPA-HF study, dapagliflozin was administered in conjunction with other heart failure therapies (see section 5.1).* *<u>Special populations</u>* *Treatment of heart failure in patients with renal impairment* *No dose adjustment is required based on renal function (see section 4.4).* *There is limited experience with dapagliflozin for the treatment of heart failure in patients with severe renal impairment (eGFR<30ml/min/1.73m2).*	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower No. 10, Jalan PJU 7/6 Mutiara Damansara 47800 Petaling Jaya, Selangor

3.	3.1 **OFEV Soft Capsules 100 mg** [Nintedanib esilate 120.40 mg (equivalent to 100 mg of nintedanib free base)] 3.2 **OFEV Soft Capsules 150 mg** [Nintedanib esilate 180.60 mg (equivalent to 150 mg of nintedanib free base)]	➢ *Indication:* *OFEV is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see section 5.1 "Clinical Trials").*	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15, Wisma UOA Damansara II No 6, Jalan Changkat Semantan Damansara Heights 50490 Kuala Lumpur
4.	4.1 **Zinforo 600 mg Powder for Concentrate for Solution for Infusion** [Ceftaroline Fosamil 600 mg]	➢ *Indication:* *Ceftaroline fosamil is indicated for the treatment of the following infection from the age of 2 months:* • *Complicated skin and soft tissue infections (cSSTI)* *Consideration should be given to official guidance on the appropriate use of antibacterial agents.* ➢ *Posology:* *<u>Dosage in paediatric patients</u>* *The recommended dosage of ceftaroline fosamil is 600 mg administered every 12 hours by intravenous infusion over 5 to 60 minutes (standard dose), with appropriate reductions for paediatric patients (see Table 1). The duration of treatment should be guided by the type of infection to be treated, its severity, and the patient's clinical response.* *For the treatment of cSSTI confirmed or suspected to be caused by Staphylococcus aureus (S. aureus) with a Minimum Inhibitory Concentration (MIC) < 2 mg/L to ceftaroline, the dose of ceftaroline fosamil is 600 mg administered every 12 hours by intravenous infusion over 5 to 60 minutes (standard dose), with appropriate reductions for paediatric patients (see Table 1).*	**PFIZER (MALAYSIA) SDN. BHD.** Level 10 & 11, Wisma Averis, Tower 2 Avenue 5, Bangsar South No.8, Jalan Kerinchi, 59200 Kuala Lumpur

For the treatment of patients with cSSTI confirmed or suspected to be caused by S. aureus with an MIC = 2 mg/L to 4 mg/L to ceftaroline, the dose of ceftaroline fosamil is 600 mg administered every 8 hours by intravenous infusion over 120 minutes (high dose), with appropriate reductions for paediatric patients (see Table 1).

*Table 1 Dosage in patients with Creatinine Clearance (CrCL) > 50 mL/min**

Indications / Recommended duration of treatment (days)	*Age group*	*Posology*	*Infusion time (minutes)[a] / Frequency*
<u>Standard dose</u> cSSTI[b] / 5 – 14	*Adolescents aged from 12 to < 18 years with bodyweight ≥ 33 kg*	*600 mg*	*5 – 60 / every 12 hours*
	Adolescents aged from 12 years to < 18 years with bodyweight < 33 kg and children ≥ 2 years to < 12 years	*12 mg/kg to a maximum of 400 mg*	*5 – 60 / every 8 hours*
	≥ 2 months to	*8 mg/kg*	*5 – 60 / every 8 hours*

	< 2 years		
<u>High dose</u> cSSTI[b] confirmed or suspected to be caused by S. aureus with an MIC = 2 mg/L or 4 mg/L to ceftaroline[d] / 5 – 14	*Adolescents and children aged from ≥ 2 years to < 18 years*	*12 mg/kg to a maximum of 600 mg*	*120 / every 8 hours*
	≥ 2 months to < 2 years	*10 mg/kg*	*120 / every 8 hours*

[a] The 5 minute infusion time is based on pharmacokinetic and pharmacodynamic analyses.
[b] Complicated skin and soft tissue infections (cSSTI) indication.
[d] Neonatal and high dose recommendations are based on pharmacokinetic and pharmacodynamic analyses.
[*] Calculated using the Cockcroft-Gault formula for adults and Schwartz formula (in mL/min/1.73 m^2) for paediatric patients.

<u>Special populations</u>

Patients with Renal impairment
The dose should be adjusted when creatinine clearance (CrCL) is ≤50 ml/min, as shown in Table 2. Dose recommendations for children and adolescents are based on PK modelling. End Stage Renal Disease (ESRD) patients can only be dosed as in Table 2.

For ESRD, there is insufficient information to recommend dosage adjustments in adolescents aged from 12 to < 18 years with bodyweight < 33 kg and in children aged from 2 to 12 years. There is insufficient information to recommend dosage adjustments in paediatric patients < 2 years with moderate or severe renal impairment or ESRD.

Table 2 Dosage in patients with renal impairment (CrCL ≤ 50 mL/min)

Indications /	*Age group*	*Creatinine clearance*	*Posolo*	*Infusion time*

Recommended duration of treatment (days)		*(mL/min)[a]*	*gy*	*(minutes)[b] / Frequency*
<u>Standard dose</u> cSSTI[c] / 5 – 14	*Adolescents aged from 12 to < 18 years with bodyweight ≥ 33 kg*	*> 30 to ≤ 50*	*400 mg*	*5 – 60 / every 12 hours*
		≥ 15 to ≤ 30	*300 mg*	
		ESRD, including haemodialysis[f]	*200 mg*	
	Adolescents aged from 12 years to < 18 years with bodyweight < 33 kg and children ≥ 2 years to < 12 years	*> 30 to ≤ 50*	*8 mg/kg to a maximum of 300 mg*	*5 – 60 / every 8 hours*
		≥ 15 to ≤ 30	*6 mg/kg to a maximum of 200 mg*	
<u>High dose</u> cSSTI[c] confirmed or suspected to be caused by S.	*Adolescents and children aged from ≥ 2 year*	*> 30 to ≤ 50*	*10 mg/kg to a maximum of 400 mg*	*120 / every 8 hours*

			aureus with an MIC = 2 mg/L or 4 mg/L to ceftaroline[e] / 5 – 14	*s to < 18 years*	*≥ 15 to ≤ 30*	*8 mg/kg to a maximum of 300 mg*	

[a] *Calculated using the Cockcroft-Gault formula for adults and Schwartz formula for paediatric patients (in mL/min/1.73 m^2). Dose is based on CrCL. CrCL should be closely monitored and the dose adjusted according to changing renal function.*

[b] *The 5 minute infusion time is based on pharmacokinetic and pharmacodynamic analyses.*

[c] *Complicated skin and soft tissue infections (cSSTI) indication.*

[e] *Based on pharmacokinetic and pharmacodynamic analyses.*

[f] *Ceftaroline is haemodialyzable; thus ceftaroline fosamil should be administered after haemodialysis on haemodialysis days.*

5.	5.1 **Toujeo 300 units/ml Solution for Injection in Pre-Filled Pen** [Insulin Glargine 10.91mg/ml]	➢ Indication: *Treatment of diabetes mellitus in adult, adolescents and children from the age of 6 years.* ➢ Posology: *<u>Special populations</u>* *Toujeo can be used in elderly people, renal and hepatic impaired patients, and children and adolescents from the age of 6 years.* *<u>Paediatric population</u>* *Toujeo can be used in adolescents and children from the age of 6 years based on the same principles as for adult patients. When switching basal insulin to Toujeo, dose reduction of basal and bolus insulin needs to be considered on an individual basis, in order to minimize the risk of hypogylcaemia. The safety and efficacy of Toujeo in children below 6 years of age have not been established. No data are available.* *<u>Method of administration</u>*	**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

		Toujeo is for subcutaneous use only. Toujeo is administered subcutaneously by injection in the abdominal wall, the deltoid or the thigh. Injection sites must be rotated within a given injection area from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis (see section 4.4 and 4.8). Toujeo must not be administered intravenously. The prolonged duration of action of Toujeo is dependent on its injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycaemia. Toujeo must not be used in insulin infusion pumps. Toujeo is available in pre-filled pens. The dose window shows the number of units of Toujeo to be injected. The Toujeo SoloStar pre-filled pen has been specifically designed for Toujeo and no dose re-calculation is required. Before using Toujeo SoloStar pre-filled pen, the instructions for use included in the package leaflet must be read carefully (see section 6.6). With Toujeo SoloStar pre-filled pen, a dose of 1-80 units per injection, in steps of 1 unit, can be injected. Toujeo must not be drawn from the cartridge of the SoloStar pre-filled pen into a syringe or severe overdose can result. A new sterile needle must be attached before each injection. Re-use of needles increases the risk of blocked needles which may cause underdosing or overdosing (see section 4.4 and 4.6). To prevent possible transmission of disease, insulin pens should never be used for more than one person, even when the needle is changed (see section 6.6).	
6.	6.1 **Cyramza 100mg/10ml concentrate for solution for infusion** [Ramucirumab 10mg/ml] 6.2 **Cyramza 500mg/50ml concentrate for solution for infusion** [Ramucirumab 10mg/ml]	➢ Indication: *Non-small cell lung cancer* *Cyramza in combination with erlotinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations.*	**ZUELLIG PHARMA SDN BHD** No. 15, Persiaran Pasak Bumi, Sek. U8 Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor

		➢ *Posology:* *Cyramza in combination with erlotinib for the treatment of NSCLC with activating EGFR mutations.* *The recommended dose of ramucirumab in combination with erlotinib is 10mg/kg every two weeks.* *EGFR mutation status should be determined prior to initiation of treatment with ramucirumab and erlotinib using a validated test method. See erlotinib prescribing information for the posology and method of administration of erlotinib.*	