Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 370 – 3 March 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Kyprolis (carfilzomib) powder for solution for infusion 60mg/vial [Carfilzomib 60mg]	**INDICATION :** Kyprolis is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with: • Daratumumab and dexamethasone. **POSOLOGY :** Kyprolis in Combination with Intravenous Daratumumab and Dexamethasone **Twice weekly 20/56 mg/m2 regimen by 30-minute infusion** Administer Kyprolis intravenously as a 30-minute infusion on Days 1, 2, 8, 9, 15 and 16 of each 28-day cycle in combination with intravenous daratumumab and dexamethasone until disease progression or unacceptable toxicity as shown in Table 4. The recommended starting dose of Kyprolis is 20 mg/m^2 on Cycle 1, Days 1 and 2. If tolerated, escalate the dose to 56mg/m2 on Cycle 1, Day 8 and thereafter. Administer dexamethasone 30 minutes to 4 hours before Kyprolis and 1 to 3 hours before intravenous daratumumab. Refer to the Prescribing Information for intravenous daratumumab and dexamethasone for additional dosage information. Table 4: Kyprolis 20/56 mg/m^2 Twice Weekly (30-Minute Infusion) in Combination with Intravenous Daratumumab and Dexamethasone	**AMGEN BIOPHARMACEUTICALS MALAYSIA SDN. BHD.** Suite 9.01, Level 9, Menara Summit, Persiaran Kewajipan USJ 1, UEP, 47600 Subang Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)

	Cycle 1											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m²)	20	20	-	56	56	-	56	56	-	-	-	-
Dexamethasone (mg)*	20	20	-	20	20	-	20	20	-	40	-	-
Daratumumab (mg/kg)	8	8	-	16	-	-	16	-	-	16	-	-
	Cycle 2											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m²)	56	56	-	56	56	-	56	56	-	-	-	-
Dexamethasone (mg)*	20	20	-	20	20	-	20	20	-	40	-	-
Daratumumab (mg/kg)	16	-	-	16	-	-	16	-	-	16	-	-
	Cycles 3-6											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m²)	56	56	-	56	56	-	56	56	-	-	-	-
Dexamethasone (mg)*	20	20	-	20	20	-	20	20	-	40	-	-
Daratumumab (mg/kg)	16	-	-	-	-	-	16	-	-	-	-	-
	Cycles 7 and onwards											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m²)	56	56	-	56	56	-	56	56	-	-	-	-
Dexamethasone (mg)*	20	20	-	20	20	-	20	20	-	40	-	-
Daratumumab (mg/kg)	16	-	-	-	-	-	-	-	-	-	-	-

*For patients > 75 years of age, administer 20 mg of dexamethasone orally or intravenously weekly after the first week.

Once weekly 20/70 mg/m^2 regimen by 30-minute infusion

Administer Kyprolis intravenously as a 30-minute infusion on Days 1, 8 and 15 of each 28-day cycle in combination with intravenous daratumumab and dexamethasone until disease progression or unacceptable toxicity as shown in Table 5. The recommended starting dose of Kyprolis is 20 mg/m^2 on Cycle 1, Day 1. If tolerated, escalate the dose to 70 mg/m2 on Cycle 1, Day 8 and thereafter. Administer dexamethasone 30 minutes to 4 hours before Kyprolis and 1 to 3 hours before intravenous daratumumab. Refer to the Prescribing Information for intravenous daratumumab and dexamethasone for additional dosage information.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)

Table 5: Kyprolis 20/70 mg/m^2 Once Weekly (30-Minute Infusion) in Combination with Intravenous Daratumumab and Dexamethasone

	Cycle 1											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m^2)	20	-	-	70	-	-	70	-	-	-	-	-
Dexamethasone (mg)*	20	20	-	20	20	-	20	20	-	20	20	-
Daratumumab (mg/kg)	8	8	-	16	-	-	16	-	-	16	-	-
	Cycle 2											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m^2)	70	-	-	70	-	-	70	-	-	-	-	-
Dexamethasone (mg)*	20	20	-	20	20	-	20	20	-	20	20	-
Daratumumab (mg/kg)	16	-	-	16	-	-	16	-	-	16	-	-
	Cycles 3-6											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m^2)	70	-	-	70	-	-	70	-	-	-	-	-
Dexamethasone (mg)*	20	20	-	40	-	-	20	20	-	40	-	-
Daratumumab (mg/kg)	16	-	-	-	-	-	16	-	-	-	-	-
	Cycles 7 and thereafter											
	Week 1			Week 2			Week 3			Week 4		
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Day 23	Days 24–28
Kyprolis (mg/m^2)	70	-	-	70	-	-	70	-	-	-	-	-
Dexamethasone (mg)*	20	20	-	40	-	-	40	-	-	40	-	-
Daratumumab (mg/kg)	16	-	-	-	-	-	-	-	-	-	-	-

*For patients > 75 years of age, administer 20 mg of dexamethasone orally or intravenously weekly after the first week.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Brilinta 60 mg Film-Coated Tablet [Ticagrelor 60mg]	**INDICATION :** <u>Coronary Artery Disease, Type 2 Diabetes Mellitus and History of Percutaneous Coronary Intervention</u> Brilinta, co-administered with low-dose acetylsalicylic acid (ASA: 75-150mg), is indicated to reduce the risk of a first myocardial infarction or stroke in patients with Coronary Artery Disease (CAD), Type 2 Diabetes Mellitus (DM) and a history of percutaneous coronary intervention (PCI), who are also at high risk of developing an atherothrombotic events. **POSOLOGY** : <u>Patients with Coronary Artery Disease (CAD) and Type 2 Diabetes Mellitus (DM) with a history of percutaneous coronary intervention (PCI)</u> Brilinta 60 mg twice daily is recommended dose for patients with CAD and type 2 DM with a history of PCI with no prior MI. No loading dose of Brilinta is required. Patient may start treatment with Brilinta 60 mg twice daily, regardless of their previous antiplatelet regimen. Treatment with Brilinta should be continued in patients with CAD and type 2 DM for as long as the patient remains at high risk of an atherothrombotic events and low risk of bleeding, for a duration up to three years. Efficacy and safety data are insufficient to establish whether the benefits of Brilinta still outweigh the risks after three years of treatment. If a switch is needed, the first dose of Brilinta should be administered 24 hours following the last dose of the other antiplatelet medication.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

<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>Jardiance 10mg film coated tablets

[Empagliflozin 10mg]</td><td>INDICATION :

<u>Heart failure</u>
Jardiance is indicated to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction.

POSOLOGY :

Heart failure

The recommended dose is 10 mg empagliflozin once daily.

<u>Special populations</u>

Patients with renal impairment

<table><tr><td><u>Heart failure</u>
Treatment of patients with heart failure and reduced ejection fraction, with or without type 2 diabetes mellitus</td><td>Not recommended for use in patients with eGFR < 20 ml/min/1.73 m^2. There are insufficient data to support use in these patients.</td></tr></table>Empagliflozin is contraindicated in patients with dialysis.</td><td>BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.
Suite 15-5 Level 15,
Wisma UOA Damansara II,
No 6, Jalan Changkat Semantan,Damansara Heights,
50490 Kuala Lumpur,
Wilayah Persekutuan Kuala Lumpur.</td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Xeljanz Film-Coated Tablets 5mg [Tofacitinib Citrate (equivalent to tofacitinib 5mg)]	**INDICATION :** Psoriatic Arthritis XELJANZ is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of XELJANZ in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **POSOLOGY** : Recommended Dosage in Rheumatoid Arthritis and Psoriatic Arthritis Table 1 displays the recommended adult daily dosage of XELJANZ and dosage adjustments for patients receiving CYP2C19 and/or CYP3A4 inhibitors, in patients with moderate or severe renal impairment (including but not limited to those with severe insufficiency who are undergoing hemodialysis) or moderate hepatic impairment, with lymphopenia, neutropenia, or anemia. Table 1: Recommended Dosage of XELJANZ in Patients with Rheumatoid Arthritis and Psoriatic Arthritis[1]	**PFIZER (MALAYSIA) SDN. BHD.** Level 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)

	XELJANZ
Adult patients	5 mg twice daily
Patients receiving: • strong CYP3A4 inhibitors (e.g., ketoconazole), or • a moderate CYP3A4 inhibitor(s) with a strong CYP2C19 inhibitor(s) (e.g., fluconazole) (see section 5)	5 mg once daily
Patients with: • moderate or severe renal impairment • moderate hepatic impairment*	5 mg once daily For patients undergoing hemodialysis, dose should be administered after the dialysis session on dialysis days. If a dose was taken before the dialysis procedure, supplemental doses are not recommended in patients after dialysis.
Patients with lymphocyte count less than 500 cells/mm^3, confirmed by repeat testing	Discontinue dosing.
Patients with ANC 500 to 1000 cells/mm^3	Interrupt dosing. When ANC is greater than 1000, resume 5 mg twice daily.
Patients with ANC less than 500 cells/mm^3	Discontinue dosing.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Patients with hemoglobin less than 8 g/dL or a decrease of more than 2 g/Dl | Interrupt dosing until hemoglobin values have normalized. [1] XELJANZ is used in combination with nonbiologic disease modifying antirheumatic drugs (DMARDs) in psoriatic arthritis. The efficacy of XELJANZ as a monotherapy has not been studied in psoriatic arthritis. * Use of XELJANZ in patients with severe hepatic impairment is not recommended.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	PLAVIX TABLET 75MG [Clopidogrel 75mg] Plavix Tablet 300mg [Clopidogrel 300mg]	**INDICATION :** In patients with moderate to high-risk Transient Ischemic Attack (TIA) or minor Ischemic Stroke (IS) Clopidogrel in combination with ASA is indicated in: • Adult patients with moderate to high-risk TIA (ABCD2[1] score ≥4) or minor IS (NIHSS[2] ≤3) within 24 hours of either the TIA or IS event ---- [1] Age, Blood pressure, Clinical features, Duration, and Diabetes mellitus diagnosis [2] National Institutes of Health Stroke Scale **POSOLOGY** : Adult patients with moderate to high-risk TIA or minor IS: • Adult patients with moderate to high-risk TIA (ABCD2 score ≥4) or minor IS (NIHSS ≤3) should be given a loading dose of clopidogrel 300 mg followed by clopidogrel 75 mg once daily and ASA (75 mg -100 mg once daily). Treatment with clopidogrel and ASA should be started within 24 hours of the event and be continued for 21 days followed by single antiplatelet therapy.	**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.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
6.	CABOMETYX 20mg film-coated tablets [Cabozantinib 20mg] CABOMETYX 40mg film-coated tablets [Cabozantinib 40mg] CABOMETYX 60mg film-coated tablets [Cabozantinib 60mg]	**INDICATION :** Renal Cell Carcinoma (RCC) CABOMETYX is indicated as monotherapy for advanced renal cell carcinoma - as first line treatment of adult patients with intermediate or poor risk - in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy CABOMETYX, in combination with nivolumab, is indicated for the first-line treatment of advanced renal cell carcinoma in adults. **POSOLOGY :** Therapy with CABOMETYX should be initiated by a physician experienced in the administration of anticancer medicinal products. Posology CABOMETYX tablets and cabozantinib capsules are not bioequivalent and should not be used interchangeably. CABOMETYX as monotherapy For RCC and HCC, the recommended dose of CABOMETYX is 60 mg once daily. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. CABOMETYX in combination with nivolumab in first-line advanced RCC The recommended dose of CABOMETYX is 40 mg once daily in combination with nivolumab administered intravenously at either 240 mg every 2 weeks **or** 480 mg every 4 weeks. CABOMETYX treatment should continue until disease progression or unacceptable toxicity. Nivolumab should be continued until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression (see the Prescribing Information for posology of nivolumab).	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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

Management of suspected adverse drug reactions may require temporary treatment interruption and/or dose reduction of CABOMETYX therapy (see Table 1). When dose reduction is necessary in monotherapy, it is recommended to reduce to 40 mg daily, and then to 20 mg daily. When CABOMETYX is administered in combination with nivolumab, it is recommended to reduce the dose to 20 mg of CABOMETYX once daily, and then to 20 mg every other day (refer to the nivolumab PI for recommended treatment modification for nivolumab).

Dose interruptions are recommended for management of CTCAE grade 3 or greater toxicities or intolerable grade 2 toxicities. Dose reductions are recommended for events that, if persistent, could become serious or intolerable.

If a patient misses a dose, the missed dose should not be taken if it is less than 12 hours before the next dose.

Table 1: Recommended CABOMETYX dose modifications for adverse reactions
<table>
<tr><th>Adverse reaction and severity</th><th>Treatment Modification</th></tr>
<tr><td>Grade 1 and Grade 2 adverse reactions which are tolerable and easily managed</td><td>Dose adjustment is usually not required.

Add supportive care as indicated.</td></tr>
<tr><td>Grade 2 adverse reactions which are intolerable and cannot be managed with a dose reduction or supportive care</td><td>Interrupt treatment until the adverse reaction resolves to Grade ≤1.

Add supportive care as indicated.

Consider re-initiating at a reduced dose.</td></tr>
<tr><td>Grade 3 adverse reactions (except clinically nonrelevant laboratory abnormalities)</td><td>Interrupt treatment until the adverse reaction resolves to Grade ≤1.

Add supportive care as indicated.

Re-initiate at a reduced dose.</td></tr>
</table>
</td><td></td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication		Product Registration Holder (PRH)
		Grade 4 adverse reactions (except clinically nonrelevant laboratory abnormalities)	Interrupt treatment. Institute appropriate medical care. If adverse reaction resolves to Grade ≤1, re-initiate at a reduced dose. If adverse reaction does not resolve, permanently discontinue CABOMETYX.	
		Liver enzymes elevations for RCC patients treated with CABOMETYX in combination with nivolumab		
		ALT or AST > 3 times ULN but ≤10 times ULN without concurrent total bilirubin ≥ 2 times ULN	Interrupt CABOMETYX and nivolumab until these adverse reactions resolves to Grade≤1 Corticosteroid therapy may be considered if immune-mediated reaction is suspected (refer to nivolumab SmPC). Re-initiate with a single medicine or sequential re-initiating with both medicines after recovery may be considered. If re-initiating with nivolumab, refer to nivolumab SmPC.	
		ALT or AST > 10 times ULN or > 3 times ULN with concurrent total bilirubin ≥ 2 times ULN	Permanently discontinue CABOMETYX and nivolumab. Corticosteroid therapy may be considered if immune-mediated reaction is suspected (refer to nivolumab SmPC).	
		Note: Toxicity grades are in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0 (NCI-CTCAE v4)		

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
7.	Xyntha 250 IU Powder and Solvent for Solution for Injection Xyntha 500 IU Powder and Solvent for Solution for Injection Xyntha 1000 IU Powder and Solvent for Solution for Injection Xyntha 2000 IU Powder and Solvent for Solution for Injection [Moroctocog Alfa]	**INDICATION :** Control and Prevention of Bleeding Episodes in Hemophilia A Routine prophylaxis to reduce bleeding episodes. **POSOLOGY :** **Routine Prophylaxis** ● Adults and adolescents (≥12 years): The recommended starting regimen is 30 IU/kg of XYNTHA administered 3 times weekly. ● Children (<12 years): The recommended starting regimen is 25 IU/kg of XYNTHA administered every other day. More frequent or higher doses may be required in children <12 years of age to account for the higher clearance in this age group [see Section 5.3 Pharmacokinetic Properties]. ● Adjust the dosing regimen (dose or frequency) based on the patient's clinical response.	**PFIZER (MALAYSIA) SDN. BHD.** Level 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
8.	CoronaVac Suspension for Injection SARS-CoV-2 Vaccine (Vero Cell), Inactivated CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated [Inactivated SARS-CoV-2 virus (CZ02 strain) (Vero cell)]	**INDICATION :** CoronaVac is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 years of age and older. The use of this vaccine should be in accordance with official recommendations. **POSOLOGY :** **Individuals 18 years of age and older** Two doses should be administered for primary immunization. The second dose is preferably given 14 - 28 days after the first dose. 0.5 mL per dose. **Children and adolescent 5 years to 17 years of age** Two doses should be administered for primary immunization. The second dose is preferably given 28 days after the first dose. 0.5 mL per dose. It has not been determined whether this product requires booster immunization. **Elderly population** No dosage adjustment is required in elderly individuals ≥ 60 years of age. There is limited data on the use of CoronaVac in individuals ≥ 60 years of age. CoronaVac, when administered to individuals ≥ 60 years of age, has shown adequate and similar neutralizing antibodies titres as in adults. At present, it is recommended that vaccination for people aged 60 and above should be considered cautiously and its necessity should be evaluated based on their health condition and exposure risk.	**PHARMANIAGA LIFESCIENCE SDN. BHD.** Lot 7, Jalan PPU 3, Taman Perindustrian Puchong Utama, 47100 Puchong, Selangor.