Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 353 – 5 February 2021)

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
1.	Tecentriq 60mg/ml Concentrate for Solution for Infusion [Atezolizumab 60mg/ml]	**INDICATION :** TECENTRIQ, as a single agent, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), with no EGFR or ALK genomic tumor aberrations. **POSOLOGY:** ***Tecentriq monotherapy*** ***NSCLC*** The recommended dose of Tecentriq in monotherapy is: • 840 mg administered by IV infusion every 2 weeks, or • 1200 mg administered by IV infusion every 3 weeks, or • 1680 mg administered by IV infusion every 4 weeks. *1L NSCLC* Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test.	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

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2.	KEYTRUDA 100mg SOLUTION FOR INFUSION [Pembrolizumab 100mg]	**INDICATION :** Colorectal Cancer KEYTRUDA as monotherapy is indicated for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in adults. **POSOLOGY:** General Patient Selection For Monotherapy Non-Small Cell Lung Carcinoma, Head and Neck Cancer, Urothelial Carcinoma or **Colorectal Cancer** Select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression in: • stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see Clinical Studies]. • metastatic NSCLC [see Clinical Studies]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see Clinical Studies]. • locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy [see Clinical Studies]. **Select patients for treatment with KEYTRUDA based on microsatellite instability-high cancer (MSI-H) or mismatch repair deficient (dMMR) tumor status in metastatic CRC [see Clinical Studies].**	**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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		Recommended Dosing KEYTRUDA is administered as an intravenous infusion over 30 minutes. The recommended dose of KEYTRUDA with head and neck cancer, cHL, urothelial carcinoma, RCC, adjuvant treatment of melanoma, endometrial carcinoma, previously untreated NSCLC or **colorectal cancer** is either: • 200mg every 3 weeks or • 400mg every 6 weeks. The recommended dose of KEYTRUDA with unresectable or metastatic melanoma and previously treated NSCLC is 2mg/kg every 3 weeks. 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. 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)]. For endometrial carcinoma patients treated with KEYTRUDA in combination with lenvatinib, the recommended initial dose of lenvatinib is 20 mg orally once daily until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression. 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. For adjuvant treatment of melanoma, KEYTRUDA should be administered for up to one year or until disease recurrence or unacceptable toxicity.	

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3.	Keytruda100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** Esophageal Cancer KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by a validated test, with disease progression after one prior line of systemic therapy. **POSOLOGY :** General Patient Selection For Monotherapy Non-Small Cell Lung Carcinoma, Head and Neck Cancer, Urothelial Carcinoma, or **Esophageal Cancer** Select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression in: • stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation • metastatic NSCLC • first-line treatment of metastatic or unresectable, recurrent HNSCC • locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy • **metastatic esophageal cancer.** Recommended Dosing KEYTRUDA is administered as an intravenous infusion over 30 minutes. The recommended dose of KEYTRUDA with head and neck cancer, cHL, urothelial carcinoma, RCC, adjuvant treatment of melanoma, endometrial carcinoma, or previously untreated NSCLC, or **esophageal cancer** is either: • 200mg every 3 weeks or • 400mg every 6 weeks. The recommended dose of KEYTRUDA with unresectable or metastatic melanoma and previously treated NSCLC is 2mg/kg every 3 weeks.	**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

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
		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. 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. For endometrial carcinoma patients treated with KEYTRUDA in combination with lenvatinib, the recommended initial dose of lenvatinib is 20 mg orally once daily until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression. 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. For adjuvant treatment of melanoma, KEYTRUDA should be administered for up to one year or until disease recurrence or unacceptable toxicity.	

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4.	4.1 Taltz 80mg solution for injection in pre-filled syringe 4.2 Taltz 80mg solution for injection in pre-filled pen [Ixekizumab 80mg]	**INDICATION :** Axial spondyloarthritis Ankylosing spondylitis (radiographic axial spondyloarthritis) Taltz is indicated for the treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy. Non-radiographic axial spondyloarthritis Taltz is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs). **POSOLOGY :** **Axial spondyloarthritis (radiographic and non-radiographic)** **The recommended dose is 160 mg (two 80 mg injections) by subcutaneous injection at Week 0, followed by 80 mg every 4 weeks (see section 5.1 for further information).** **For all indications (plaque psoriasis, psoriatic arthritis, axial spondyloarthritis)** consideration should be given to discontinuing treatment in patients who have shown no response after 16 to 20 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 20 weeks.	**ZUELLIG PHARMA SDN BHD** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor

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5.	5.1 Fiasp® 100 units/ml, 10ml Vial 5.2 Fiasp® Penfill® 100 units/ml, Solution for injection 5.3 Fiasp® FlexTouch ® 100 units/ml, Solution for injection [Insulin aspart 100 U/mL]	**INDICATION :** Treatment of diabetes mellitus in adult, adolescents and children aged 1 year and above. **POSOLOGY :** Fiasp® is a mealtime insulin for subcutaneous administration up to 2 minutes before the start of the meal, with the option to administer up to 20 minutes after starting the meal (see section 5.1). Dosing with Fiasp® is individual and determined in accordance with the needs of the patient. Fiasp® given by subcutaneous injection should be used in combination with intermediate- or long-acting insulin given at least once a day. In a basal-bolus treatment regimen approximately 50% of this requirement may be provided by Fiasp® and the remaining by intermediate- or long-acting insulin. The individual total daily insulin requirement in adults, **adolescents and children** may vary and is usually between 0.5 and 1.0 unit/kg/day. Blood glucose monitoring and insulin dose adjustment are recommended to achieve optimal glycaemic control. Adjustment of dose may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness. Blood glucose levels should be monitored adequately under these conditions. The duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. Patients on basal-bolus treatment who forget a mealtime dose are advised to monitor their blood glucose level to decide if an insulin dose is needed. Patients should resume their usual dosing schedule at the next meal. The potency of insulin analogues, including Fiasp®, is expressed in units. One (1) unit of Fiasp® corresponds to 1 international unit of human insulin or 1 unit of other fast-acting insulin analogues. **The early onset of action must be considered when prescribing Fiasp® (see section 5.1).**	**NOVO NORDISK PHARMA (MALAYSIA) SDN. BHD.** Menara 1 Sentrum, Level 16, No. 201, Jalan Tun Sambathan, 50470, Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

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<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Marketing Authorization Holder</th></tr>
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<u>Initiation</u>

<u>Patients with type 1 diabetes mellitus</u>
The recommended starting dose in insulin naïve patients with type 1 diabetes is approximately 50% of the total daily insulin dose and should be divided between the meals based on the size and composition of the meals. The remainder of the total daily insulin dose should be administered as intermediate- or long-acting insulin. As a general rule, 0.2 to 0.4 units of insulin per kilogram of body weight can be used to calculate the initial total daily insulin dose in insulin naïve patients with type 1 diabetes.

<u>Patients with type 2 diabetes mellitus</u>
The suggested initial dose is 4 units at one or more meals. The number of injections and subsequent titration will depend on the individual glycaemic target and the size and composition of the meals.

Dose adjustment may be considered daily based on self-measured plasma glucose (SMPG) on the previous day(s) according to Table 1.

Pre-breakfast dose should be adjusted according to the pre-lunch SMPG the previous day
Pre-lunch dose should be adjusted according to the pre-dinner SMPG the previous day
Pre-dinner dose should be adjusted according to the bedtime SMPG the previous day

<table>
<tr><td colspan="2">SMPG (see above)</td><td>Dose adjustment</td></tr>
<tr><td>mmol/l</td><td>mg/dl</td><td>Unit</td></tr>
<tr><td>< 4.0</td><td>< 71</td><td>-1</td></tr>
<tr><td>4.0–6.0</td><td>71–108</td><td>No adjustment</td></tr>
<tr><td>> 6.0</td><td>> 108</td><td>+1</td></tr>
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		Special populations Elderly patients (≥ 65 years old) The safety and efficacy of Fiasp® have been established in elderly patients aged 65 to 75 years. Close glucose monitoring is recommended and the insulin dose should be adjusted on an individual basis (see sections 5.1 and 5.2). The therapeutic experience in patients ≥ 75 years of age is limited. Renal and hepatic impairment Renal or hepatic impairment may reduce the patient's insulin requirements. In patients with renal or hepatic impairment, glucose monitoring should be intensified and the dose adjusted on an individual basis (see section 5.2). **Paediatric population** **Fiasp® can be used in adolescents and children from the age of 1 year (see section 5.1). There is no clinical experience with the use of Fiasp® in children below the age of 2 years. Fiasp® is recommended to be administered prior to the meal (0-2 minutes), with the flexibility to administer up to 20 minutes after starting the meal in situations, when there is uncertainty about the meal intake.**	

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6.	Duratocin 100mcg/ml [Carbetocin 100mcg]	**INDICATION :** Prevention of postpartum haemorrhage due to uterine atony. **POSOLOGY :** Vaginal delivery: Withdraw 1 ml of DURATOCIN containing 100 micrograms carbetocin and administer by intravenous injection or intramuscular injection, under adequate medical supervision in a hospital. METHOD OF ADMINISTRATION For intravenous or intramuscular administraion. <u>Paediatric Population</u> There is no relevant use of carbetocin in children below 12 years of age. The safety and efficacy of carbetocin in adolescents has not yet been established.	**FERRING SDN. BHD.** 21-6, Block B Jaya One, No. 72A, Jalan Universiti, 46200 Petaling Jaya, Selangor.