

Maklumat tambahan indikasi

Year 2018

Products Approved For Additional Indication (DCA 323 – 23 April 2018)

N O	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 KEYTRUDA 100MG SOLUTION FOR INFUSION [Pembrolizumab 100mg]</p>	<p>➤ Indication:</p> <p><u><i>Urothelial Carcinoma</i></u> <i>KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.</i></p> <p>➤ Posology:</p> <p><i>Recommended Dosing</i> <i>KEYTRUDA is administered as an intravenous infusion over 30 minutes every 3 weeks.</i> <i>The recommended dose of KEYTRUDA is:</i></p> <ul style="list-style-type: none"> • <i>200mg for head and neck cancer or previously untreated NSCLC or urothelial carcinoma</i> • <i>2mg/kg for melanoma or previously treated NSCLC</i> <p><i>Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e an initial transient increase in tumour size or small new lesions within the first few months followed by tumour shrinkage) have been observed. Clinically stable patients with initial evidence of disease progression should remain on treatment until disease progression is confirmed.</i></p>	<p>MERCK SHARP & DOHME (MALAYSIA) SDN BHD Lot B-22-1 & B22-2, Level 22 The Ascent Paradigm No1, Jalan SS7/26A, Kelana Jaya 47301, Petaling Jaya, Selangor</p>

2.	2.1 VICTOZA 6MG/ML SOLUTION FOR INJECTION IN PRE-FILLED PEN [Liraglutide 6mg/ml]	➤ Indication: <i><u>Prevention of cardiovascular events</u></i> <i>Victoza is indicated to reduce the risk of major adverse cardiovascular events (MACE), composed of cardiovascular (CV) death, non-fatal myocardial infarction and non-fatal stroke, in adults with type 2 diabetes who have established CV disease or are at high risk for CV disease.</i>	NOVO NORDISK PHARMA (MALAYSIA) SDN. BHD. Menara 1 Sentrum, Level 16 No. 201, Jalan Tun Sambathan 50470 Kuala Lumpur
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