Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 362 – 5 Ogos 2021)

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
1.	Keytruda 100mg Solution for Infusion [Pembrolizumab 100mg/vial]	**INDICATION :** **Classical Hodgkin Lymphoma (cHL)** KEYTRUDA as monotherapy is indicated for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option. **POSOLOGY:** Adults: 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, colorectal cancer, or esophageal cancer in adults is either: • 200mg every 3 weeks or • 400mg every 6 weeks. Pediatrics Patients: In cHL, the recommended dose of KEYTRUDA in pediatric patients is 2 mg/kg (up to a maximum of 200 mg), administered as an intravenous infusion over 30 minutes every 3 weeks. *(Note: There is no change to the approved posology for adults. For the pediatric dose, it is the same with the weight based dosing for the approved dose for adult in melanoma and previously treated NSCLC)*	**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
2.	Xolair 150mg Powder and Solvent for Solution for Injection Xolair 75 mg Powder and Solvent for Solution for Injection [Omalizumab 125mg/mL]	**INDICATION :** **Chronic rhinosinusitis with nasal polyps (CRSwNP)** Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with CRSwNP for whom therapy with INC does not provide adequate disease control. **POSOLOGY** : (The statement in **bold** has been added for this indication) For subcutaneous administration only. Do not administer by the intravenous or intramuscular route. Dosage regimen for Allergic Asthma **and chronic rhinosinusitis with nasal polyps (CRSwNP)** Dosing for asthma and **CRSwNP** follows the same dosing principles. The appropriate dose and dosing frequency of Xolair **for these conditions** is determined by baseline immunoglobulin E (IgE) (IU/mL), measured before the start of treatment, and body weight (kg). Prior to initial dosing, patients should have their IgE level determined by any commercial serum total IgE assay for their dose assignment. Based on these measurements 75 to 600 mg of Xolair in 1 to 4 injections may be needed for each administration. See Table 1 for a conversion chart and Tables 2 and 3 for the dose determination. For doses of 225, 375 or 525 mg Xolair, 150 mg can be used in combination with Xolair 75 mg. Patients whose baseline IgE levels or body weight in kilograms are outside the limits of the dosing table should not be given Xolair.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya Selangor Darul Ehsan Malaysia

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		Table 1: Conversion from dose to number of vials, number of injections and total injection volume for each administration	

Dose (mg)	Number of vials		Number of injections	Total injection volume (mL)
	75 mg [a]	150 mg [b]		
75	1[c]	0	1	0.6
150	0	1	1	1.2
225	1[c]	1	2	1.8
300	0	2	2	2.4
375	1[c]	2	3	3.0
450	0	3	3	3.6
525	1[c]	3	4	4.2
600	0	4	4	4.8

[a] 0.6 ml = maximum delivered volume per vial (Xolair 75 mg).

[b] 1.2 ml = maximum delivered volume per vial (Xolair 150 mg).

[c] or use 0.6 mL from a 150 mg vial.

Treatment duration, monitoring and dose adjustments

In clinical trials for allergic asthma there were reductions in asthma exacerbation events and rescue medication use with improvements in symptom scores during the first 16 weeks of treatment. At least 12 weeks of treatment is required to adequately assess whether or not a patient is responding to Xolair.

In clinical trials for CRSwNP, changes in nasal polyps score (NPS) and nasal congestion score (NCS) were observed as early as the first assessment at 4 weeks. The need for continued therapy should be periodically reassessed based upon the patient's disease severity and level of symptom control.

Xolair is intended for long-term treatment. Discontinuation generally results in a return to elevated free IgE levels and associated symptoms.

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		Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during Xolair treatment cannot be used as a guide for dose determination. Dose determination after treatment interruptions lasting less than one year should be based on serum IgE levels obtained at the initial dose determination. Total serum IgE levels may be re-tested for dose determination if treatment with Xolair has been interrupted for one year or more. *Doses should be adjusted for significant changes in body weight (see Tables 2 and 3).* *Table 2 ADMINISTRATION EVERY 4 WEEKS – Allergic Asthma **and CRWwNP**. Xolair doses (milligrams per dose) administered by subcutaneous injection every 4 weeks*	

	Body weight (kg)									
Baseline IgE (IU/ml)	≥20-25*	>25-30*	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
≥30–100	75	75	75	150	150	150	150	150	300	300
>100–200	150	150	150	300	300	300	300	300	450	600
>200–300	150	150	225	300	300	450	450	450	600	
>300–400	225	225	300	450	450	450	600	600		
>400–500	225	300	450	450	600	600				
>500–600	300	300	450	600	600					
>600–700	300		450	600						

ADMINISTRATION EVERY 2 WEEKS SEE TABLE 3

*Body weights below 30 kg were not studied in the pivotal trials for nasal polyps

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
		Table 3 ADMINISTRATION EVERY 2 WEEKS – Allergic Asthma and CRSwNP. Xolair doses (milligrams per dose) administered by subcutaneous injection every 2 weeks	

Baseline IgE (IU/ml)	Body weight (kg)									
	≥20-25*	>25-30*	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
≥ 30-100	ADMINISTRATION EVERY 4 WEEKS SEE TABLE 2									
> 100-200										
> 200-300										375
> 300-400									450	525
> 400-500							375	375	525	600
> 500-600						375	450	450	600	
> 600-700		225			375	450	450	525		
> 700-800	225	225	300	375	450	450	525	600		
> 800-900	225	225	300	375	450	525	600			
> 900-1000	225	300	375	450	525	600				
> 1000-1100	225	300	375	450	600	Insufficient data to recommend a dose				
> 1100-1200	300	300	450	525	600					
> 1200-1300	300	375	450	525						
> 1300-1500	300	375	525	600						

*Body weights below 30 kg were not studied in the pivotal trials for nasal polyps