Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 354 – 2 March 2021)

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
1.	Cosentyx 150mg/ml Solution for Injection in pre-filled pen Cosentyx 150mg/ml Solution for Injection in pre-filled syringe Fraizeron 150mg Powder for Solution for Injection [Secukinumab 150mg]	**INDICATION :** Non-radiographic axial spondyloarthritis (nr-axSpA) Cosentyx/Fraizeron is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs). **POSOLOGY:** Axial spondyloarthritis (axSpA) Ankylosing spondylitis (AS, radiographic axial spondyloarthritis) The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4 followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg. Each 300 mg dose is given as two subcutaneous injections of 150 mg. **Non-radiographic axial spondyloarthritis (nr-axSpA)** **The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing**. Special populations Renal impairment / hepatic impairment Cosentyx/Fraizeron has not been studied specifically in these patient populations.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33, No. 1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

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		Pediatric patients Safety and effectiveness in pediatric patients below the age of 18 years have not yet been established. Geriatric patients (65 years or above) No dose adjustment is required. Method of administration Pre-filled syringe & pre-filled pen Cosentyx/Fraizeron is administered by subcutaneous injection. If possible, areas of the skin that show psoriasis should be avoided as injection sites. After proper training in subcutaneous injection technique, patients may self-inject Cosentyx/Fraizeron if a physician determines that it is appropriate. However, the physician should ensure appropriate follow-up of patients. Patients should be instructed to inject the full amount of Cosentyx/Fraizeron according to the instructions provided in the package leaflet. Comprehensive instructions for administration are given in the package leaflet.	

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2.	Victoza 6mg/mL solution for injection in pre-filled pen [Liraglutide 6mg/mL]	**INDICATION :** Victoza is indicated for treatment of **adolescents and children aged 10 years and above** with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or insulin when these, together with diet and exercise, do not provide adequate glycaemic control (see sections Special warnings and precautions for use and Pharmacodynamic properties for available data on the different combinations). **POSOLOGY:** To improve gastro-intestinal tolerability, the starting dose is 0.6 mg liraglutide daily. After at least one week, the dose should be increased to 1.2 mg. Some patients are expected to benefit from an increase in dose from 1.2 mg to 1.8 mg and based on clinical response, after at least one week, the dose can be increased to 1.8 mg to further improve glycaemic control. Daily doses higher than 1.8 mg are not recommended. When Victoza® is added to a sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia (see Special warnings and precautions for use). **Combination therapy with sulfonylurea is only valid for adult patients.** Self-monitoring of blood glucose is not needed in order to adjust the dose of Victoza®. Blood glucose self-monitoring is necessary to adjust the dose of sulfonylurea and insulin, particularly when Victoza® therapy is started and insulin is reduced. A stepwise approach to insulin dose reduction is recommended. No dose adjustment is required during Ramadan when Victoza® is added to metformin for treatment of type 2 diabetes mellitus (see Other clinical data). It is recommended to finalise dose escalation of Victoza® before patients start Ramadan fasting	**NOVO NORDISK PHARMA (MALAYSIA) SDN. BHD.** Menara 1 Sentrum, Level 16, No. 201, Jalan Tun Sambathan, 50470 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
		Special populations Elderly patients (>65 years old): No dose adjustment is required based on age (see Pharmacokinetic properties). Renal impairment: No dose adjustment is required for patients with mild, moderate or severe renal impairment. There is no therapeutic experience in patients with end-stage renal disease, and Victoza® is therefore not recommended for use in these patients (see Pharmacodynamic properties and Pharmacokinetic properties). Hepatic impairment: No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Victoza® is not recommended for use in patients with severe hepatic impairment (see Pharmacokinetic properties). Paediatric population: **No dose adjustment is required for adolescents and children aged 10 years and above. No data are available for children below 10 years of age (see Pharmacodynamic properties and Pharmacokinetic properties)**	

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Marketing Authorization Holder</th></tr>
<tr><td>3.</td><td>Tecentriq 60mg/mL Concentrate for Solution for Infusion

[ATEZOLIZUMAB 1200mg/20mL]</td><td>
INDICATION :

Hepatocellular carcinoma
Tecentriq, in combination with Avastin, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

POSOLOGY :

HCC
<u>Tecentriq in combination with Avastin</u>
Administer TECENTRIQ 1,200 mg, followed by 15 mg/kg Avastin on the same day every 3 weeks. If Avastin is discontinued, administer TECENTRIQ as:
• 840 mg every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks

Duration of Treatment
Patients are treated with Tecentriq until loss of clinical benefit (see section 3.1.2 Clinical / Efficacy Studies) or unacceptable toxicity.

Dose modifications for immune-related adverse reactions

Recommendations for specific adverse drug reactions (see sections 2.4.1 Warnings and Precautions, General and 2.6.1 Undesirable Effect, Clinical Trials) are presented in Table 1.

Table 1 Recommended dose modifications for specific adverse drug reactions
<table>
<tr><th>Adverse Reaction</th><th>Severity</th><th>Treatment Modification</th></tr>
<tr><td rowspan="2">Immune-related pneumonitis</td><td>Grade 2</td><td>Withhold[1]</td></tr>
<tr><td>Grade 3 or 4</td><td>Permanently discontinue</td></tr>
<tr><td rowspan="2">Immune-related hepatitis in patients without HCC</td><td>Grade 2 (ALT or AST >3x ULN or blood bilirubin >1.5x ULN for more than 5-7 days)</td><td>Withhold[1]</td></tr>
<tr><td>Grade 3 or 4 (ALT or AST</td><td>Permanently discontinue</td></tr>
</table>
</td><td>ROCHE (MALAYSIA) SDN. BHD.
Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway 47500 Subang Jaya, Selangor.</td></tr>
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No.	Product [Active Ingredient]	Additional Indication			Marketing Authorization Holder
			>5.0x ULN or blood bilirubin >3x ULN)		
		Immune-related hepatitis in patients with HCC	**If AST/ALT is within normal limits at baseline and increases to >3x to ≤10x ULN** **If AST/ALT is >1 to ≤3x ULN at baseline and increases to >5x to ≤10x ULN** **If AST/ALT is >3x to ≤5x ULN at baseline and increases to >8x to ≤10x ULN**	**Withhold[1]**	
			If AST/ALT increases to >10x ULN or total bilirubin increases to >3x ULN	**Permanently discontinue**	
		Immune-related colitis	Grade 2 diarrhea or colitis	Withhold[1]	
			Grade 3 diarrhea of colitis	Withhold[1] Initiate IV corticosteroids and convert to oral corticosteroids after improvement	
			Grade 4 diarrhea of colitis	Permanently discontinue	
		Immune-related hypothyroidism	Symptomatic	Withhold[2] Initiate thyroid hormone replacement therapy	

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		Immune-related hyperthyroidism	Symptomatic	Withhold[2] Initiate anti-thyroid therapy as needed	
		Immune-related adrenal insufficiency	Symptomatic	Withhold[1]	
		Immune-related hypophysitis	Grade 2 or 3	Withhold[1]	
			Grade 4	Permanently discontinue	
		Immune-related type 1 diabetes	For ≥ Grade 3 hyperglycemia (fasting glucose >250 mg/dL)	Withhold[2] Initiate insulin	
		Immune-related meningitis, encephalitis, myasthenic syndrome / myasthenia gravis, Guillain-Barré syndrome	All grades	Permanently discontinue	
		Immune-related pancreatitis	Grade 2 or 3 ≥ Grade 3 serum amylase or lipase levels increased (>2.0 ULN)	Withhold[1]	
			Grade 4 or any grade recurrent pancreatitis	Permanently discontinue	
		Immune-related myocarditis	Grade 2	Withhold	

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	Grade 3 or 4	Permanently discontinue
Immune-related myositis	Grade 2 or 3	Withhold[1]
	Grade 4 or grade 3 recurrent myositis	Permanently discontinue
Immune-related nephritis	Grade 2 (creatinine level >1.5 - 3.0x baseline or >1.5 - 3.0x ULN)	Withhold[1]
	Grade 3 (creatinine level >3.0x baseline or >3.0 - 6.0x ULN) or 4 (creatinine level >6.0x ULN)	Permanently discontinue
Infusion-related reactions	Grade 1 or 2	Reduce rate of infusion or withhold treatment Premedication with antipyretic and antihistamines may be considered for subsequent doses
	Grade 3 or 4	Permanently discontinue
Rash	Grade 3	Withhold
	Grade 4	Permanently discontinue

[1] Treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent.

[2] Treatment with Tecentriq may be resumed when symptoms are controlled and the patient is clinically stable.

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		For other immune-related reactions, based on the type and severity of the reaction, treatment with Tecentriq should be withheld for Grades 2 or 3 immune-related adverse reactions and corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. If symptoms improve to ≤ Grade 1, taper corticosteroids as clinically indicated. Treatment with Tecentriq may be resumed if the event improves to ≤ Grade 1 within 12 weeks, and corticosteroids have been reduced to ≤10 mg oral prednisone or equivalent per day. Treatment with Tecentriq should be permanently discontinued for Grade 4 immune-related adverse reactions, or when unable to reduce corticosteroid dose to the equivalent for ≤10 mg prednisone per day within 12 weeks after onset.	
4.	Zoladex LA 10.8 mg [Goserelin (LHRH analogue) 10.8 mg]	**INDICATION :** Premenopausal Breast cancer: Zoladex LA 10.8 mg is indicated in the management of estrogen-receptor-positive breast cancer in premenopausal women. **POSOLOGY :** Adult Females: One 10.8 mg depot of Zoladex LA injected subcutaneously into the anterior abdominal wall, every 12 weeks.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

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5.	Broadline Spot-On Solution For Cats <2.5kg Broadline Spot-On Solution For Cats 2.5-7.5kg [Fipronil 24.9 mg/0.3 ml; S- Methoprene 30.0 mg/ 0.3 ml, Eprinomectin 1.20 mg/ 0.3 ml; Praziquantel 24.9 mg/ 0.3 ml]	**INDICATION :** Treatment of infestations with gastrointestinal nematode (L4 larvae and adults of Ancylostoma ceylanicum)	**RHONE MA MALAYSIA SDN. BHD.** Lot 18A & 18B, Jalan 241, Seksyen 51A, 46100 Petaling Jaya, Selangor.