Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 365 – 8 Oktober 2021)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Opdivo 10mg/ml, Concentrate for solution for infusion [Nivolumab 10mg/ml]	**INDICATION :** Adjuvant treatment of melanoma OPDIVO as monotherapy is indicated for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. **POSOLOGY:** Treatment must be initiated and supervised by physicians experienced in the treatment of cancer. Posology The recommended dose of OPDIVO is 3 mg/kg administered intravenously over 30 minutes every 2 weeks. Treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient. **For adjuvant therapy, the maximum treatment duration with OPDIVO is 12 months.** Dose escalation or reduction is not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability. Guidelines for permanent discontinuation or withholding of doses are described in Table 1. Detailed guidelines for the management of immune-related adverse reactions are described in section 4.4.	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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Table 1: Recommended treatment modifications for OPDIVO

Immune-related adverse reaction	**Severity**	**Treatment modification**
Immune-related pneumonitis	Grade 2 pneumonitis	Withhold dose(s) until symptoms resolve, radiographic abnormalities improve, and management with corticosteroids is complete
	Grade 3 or 4 pneumonitis	Permanently discontinue treatment
Immune- related colitis	Grade 2 or 3 diarrhoea or colitis	Withhold dose(s) until symptoms resolve and management with corticosteroids, if needed, is complete
	Grade 4 diarrhoea or colitis	Permanently discontinue treatment
Immune-related hepatitis	Grade 2 elevation in aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin	Withhold dose(s) until laboratory values return to baseline and management with corticosteroids, if needed, is complete
	Grade 3 or 4 elevation in AST, ALT, or total bilirubin	Permanently discontinue treatment
Immune-related nephritis and renal dysfunction	Grade 2 or 3 creatinine elevation	Withhold dose(s) until creatinine returns to baseline and management with corticosteroids is complete
	Grade 4 creatinine elevation	Permanently discontinue treatment
Immune-related endocrinopathies	Symptomatic Grade 2 or 3 hypothyroidism, hyperthyroidism, hypophysitis Grade 2 adrenal insufficiency Grade 3 diabetes	Withhold dose(s) until symptoms resolve and management with corticosteroids (if needed for symptoms of acute inflammation) is complete. Treatment should be continued in the presence of hormone replacement therapy[a] as long as no symptoms are present

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			Grade 4 hypothyroidism, hyperthyroidism, hypophysitis Grade 3 or 4 adrenal insufficiency Grade 4 diabetes	Permanently discontinue treatment	
		Immune-related skin adverse reactions	Grade 3 rash	Withhold dose(s) until symptoms resolve and management with corticosteroids is complete	
			Grade 4 rash	Permanently discontinue treatment	
			Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)	Permanently discontinue treatment (see section 4.4)	
		Immune-related myocarditis	Grade 2 myocarditis	Withhold dose(s) until symptoms resolve and management with corticosteroids is complete[b]	
			Grade 3 or 4 myocarditis	Permanently discontinue treatment	
		Other immune-related adverse reactions	Grade 3 (first occurrence)	Withhold dose(s)	
			Grade 4 or recurrent Grade 3; persistent Grade 2 or 3 despite treatment modification; inability to reduce corticosteroid dose to 10 mg prednisone or equivalent per day	Permanently discontinue treatment	
		Note: Toxicity grades are in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0 (NCI-CTCAE v4). Recommendation for the use of hormone replacement therapy is provided in section 4.4. The safety of re-initiating nivolumab therapy in patients previously experiencing immune-related myocarditis is not known.			

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		OPDIVO should be permanently discontinued for: • Grade 4 or recurrent Grade 3 adverse reactions; • Persistent Grade 2 or 3 adverse reactions despite management. <u>Special populations</u> Paediatric population The safety and efficacy of OPDIVO in children below 18 years of age have not been established. No data are available. Elderly No dose adjustment is required for elderly patients (≥ 65 years). Data from patients 75 years of age or older are too limited to draw conclusions on this population. Renal impairment Based on the population pharmacokinetic (PK) results, no dose adjustment is required in patients with mild or moderate renal impairment (see section 5.2). Data from patients with severe renal impairment are too limited to draw conclusions on this population. Hepatic impairment Based on the population PK results, no dose adjustment is required in patients with mild hepatic impairment (see section 5.2). Data from patients with moderate or severe hepatic impairment are too limited to draw conclusions on these populations. OPDIVO must be administered with caution in patients with moderate (total bilirubin > 1.5 × to 3 × the upper limit of normal [ULN] and any AST) or severe (total bilirubin > 3 × ULN and any AST) hepatic impairment.	

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		<u>Method of administration</u> OPDIVO is for intravenous use only. It is to be administered as an intravenous infusion over a period of 30 minutes. The infusion must be administered through a sterile, non-pyrogenic, low protein binding in-line filter with a pore size of 0.2-1.2 µm. OPDIVO must not be administered as an intravenous push or bolus injection. The total dose of OPDIVO required can be infused directly as a 10 mg/mL solution or can be diluted to as low as 1 mg/mL with sodium chloride 9 mg/mL (0.9%) solution for injection or glucose 50 mg/mL (5%) solution for injection. For instructions on the preparation and handling of the medicinal product before administration, see section 6.6.	

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<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>2.</td><td>Dupixent 200mg Solution for Injection in Pre-Filled Syringe [Dupilumab 175mg/mL]</td><td>
INDICATION :

DUPIXENT is indicated for the treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.

POSOLOGY :

DUPIXENT is administered by subcutaneous injection.

<u>Dosing in Adults</u>
The recommended dose of DUPIXENT for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W).

<u>Dosing in Pediatric Patients (6 to 17 Years of Age)</u>
The recommended dose of DUPIXENT for patients 6 to 17 years of age is specified in Table 1.

Table 1: Dose of DUPIXENT for Subcutaneous Administration in Paediatric Patients (6 to 17 Years of Age)
<table>
<tr><th>Body Weight</th><th>Initial Dose</th><th>Subsequent Dose</th></tr>
<tr><td>15 to less than 30 kg</td><td>600 mg (two 300 mg injection)</td><td>300 mg every 4 weeks (Q4W)</td></tr>
<tr><td>30 to less than 60kg</td><td>400mg (two 200mg injections)</td><td>200 mg every other week (Q2W)</td></tr>
<tr><td>60kg or more</td><td>600mg (two 300mg injections)</td><td>300 mg every other week (Q2W)</td></tr>
</table>
<u>Concomitant Topical Therapies</u>
DUPIXENT can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas.
</td><td>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.</td></tr>
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3.	COMIRNATY Concentrate for Dispersion for Injection COMIRNATY Concentrate for Dispersion for Injection [Inactivated SARS-CoV-2 virus (CZ02 strain) (Vero cell)]	**INDICATION :** Comirnaty is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older. The use of this vaccine should be in accordance with official recommendations. **POSOLOGY :** *Individuals 12 years of age and older* *Comirnaty is administered intramuscularly after dilution as a primary course of 2 doses (0.3 mL each). It is recommended to administer the second dose 3 weeks after the first dose.* ***A booster dose of Comirnaty may be administered intramuscularly at least 6 months after the second dose in individuals 18 years of age and older.*** ***The decision when and for whom to implement a third dose of Comirnaty should be made based on available vaccine effectiveness data, taking into account limited safety data.*** ***The interchangeability of Comirnaty with other COVID-19 vaccines to complete the primary vaccination course or the booster dose has not been established. Individuals who have received 1 dose of Comirnaty should receive a second dose of Comirnaty to complete the primary vaccination course and for any additional doses.*** ***Severely immunocompromised aged 12 years and older*** ***A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised.*** *Paediatric population* *The safety and efficacy of Comirnaty in paediatric participants aged less than 12 years have not yet been established. Limited data are available.*	**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.

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		<u>Elderly population</u> *No dosage adjustment is required in elderly individuals ≥65 years of age.* ***The safety and effectiveness of a booster dose of Comirnaty in individuals 65 years of age and older is based on safety and effectiveness data in adults at least 18 through 55 years of age.*** ***SPECIAL WARNINGS AND PRECAUTIONS FOR USE*** *<u>Immunocompromised individuals</u>* *The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Comirnaty may be lower in immunosuppressed individuals.* ***The recommendation to consider a third dose in severely immunocompromised individuals is based on limited serological evidence from a case-series in the literature from the clinical management of patients with iatrogenic immunocompromisation after solid organ transplantation.***	

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4.	RINVOQ® 15mg Extended Release Film Coated Tablets [Upadacitinib Hemihydrate 15.4mg (corresponds to 15 mg of upadacitinib on an anhydrous basis)]	**INDICATION:** Psoriatic arthritis RINVOQ® is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ® may be used as monotherapy or in combination with methotrexate. **POSOLOGY :** Treatment with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of conditions for which upadacitinib is indicated. The recommended dose of upadacitinib is 15 mg once daily.	**ABBVIE SDN. BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

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5.	PROTOPIC OINTMENT 0.1% [Tacrolimus 0.1g] PROTOPIC OINTMENT 0.03% [Tacrolimus 0.03g]	**INDICATION:** <u>Maintenance treatment</u> Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected). **POSOLOGY:** <u>Maintenance treatment</u> Patients who are responding to up to 6 weeks treatment using tacrolimus ointment twice daily (lesions cleared, almost cleared or mildly affected) are suitable for maintenance treatment. <u>Adult and adolescents (16 years of age and above)</u> Adult patients should use Protopic 0.1% ointment. Protopic ointment should be applied once a day twice weekly (e.g. Monday and Thursday) to areas commonly affected by atopic dermatitis to prevent progression to flares. Between applications there should be 2-3 days without Protopic treatment. After 12 months treatment, a review of the patient's condition should be conducted by the physician and a decision taken whether to continue maintenance treatment in the absence of safety data for maintenance treatment beyond 12 months. If signs of a flare reoccur, twice daily treatment should be re-initiated (see Flare treatment section above). <u>Paediatric population</u> Children (2 years of age and above) should use the lower strength Protopic 0.03% ointment. Protopic ointment should be applied once a day twice weekly (e.g. Monday and Thursday) to areas commonly affected by atopic dermatitis to prevent progression to flare. Between	**DKSH MALAYSIA SDN BHD** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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		applications there should be 2-3 days without Protopic treatment. The review of the child's condition after 12 months treatment should include suspension of treatment to assess the need to continue this regimen and to evaluate the course of the disease. Protopic ointment should not be used in children aged below 2 years until further data are available. <u>Elderly patients (65 years of age and above)</u> Specific studies have not been conducted in elderly patients (see Flare treatment section above).	

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6.	Lusefi 2.5mg film-coated tablet [Luseogliflozin hydrate 2.575mg (equivalent to luseogliflozin 2.5mg)] Lusefi 5mg film-coated tablet [Luseogliflozin hydrate 5.150mg (equivalent to luseogliflozin 5mg)]	**INDICATION:** Add-on combination therapy In combination with glucose-lowering medicinal products including insulin preparations in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise plus monotherapy does not provide adequate glycemic control.	**HOE PHARMACEUTICALS SDN. BHD.** Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor.

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7.	Imbruvica 140mg Capsules Imbruvica 140mg Capsules [Ibrutinib 140mg]	**INDICATION:** IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM). **POSOLOGY:** Waldenström's macroglobulinaemia (WM) The recommended dose for the treatment of WM in combination, is 420 mg (three capsules) once daily.	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor.