Maklumat tambahan indikasi
Year 2020
Products Approved For Additional Indication (DCA 346 – 9 July 2020)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **ADACEL SUSPENSION FOR INJECTION** [Each single 0.5mL dose contains: Tetanus Toxoid 5Lf Diphtheria toxoid 2Lf Acellular Pertussis PT 2.5µg FHA 5µg PRN 3µg FIM 5µg PT: Pertussis Toxoid, FHA: Filamentous Haemagglutinin, PRN: Pertacin, FIM: Fimbriae Types 2 and 3]	➢ Indication: *Passive protection against pertussis in early infancy following maternal immunization during pregnancy.* *ADACEL® should be used in accordance with official recommendations.* ➢ Posology: *ADACEL® may be administered to pregnant women during the second or third trimester to provide passive protection of infants against pertussis.*	**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
2.	2.1 **Gardasil 9 [Human Papillomavirus 9-valent Vaccine, Recombinant]** [Each 0.5mL dose contains: HPV 6 30 µg HPV 11 40 µg HPV 16 60 µg HPV 18 40 µg HPV 31 20 µg HPV 33 20 µg HPV 45 20 µg HPV 52 20 µg HPV 58 20 µg]	➢ Indication: *GARDASIL 9 is a vaccine indicated in girls and women from 9 through 45 years of age for the prevention of cervical, vulvar, vaginal and <u>anal</u> cancer, precancerous or dysplastic lesions and genital warts caused by Human Papillomavirus (HPV).* *GARDASIL 9 is indicated to prevent the following diseases:* • *Cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58* • *Genital warts (condyloma acuminata) caused by HPV types 6 and 11* *And the following precancerous or dysplastic lesions caused*	**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

		by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58: • *Cervical intraepithelial neoplasia (CIN) grade 2/3 and Cervical adenocarcinoma in situ (AIS)* • *Cervical intraepithelial neoplasia (CIN) grade 1* • *Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3* • *Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3* • *Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.* *GARDASIL 9 is indicated in boys and men from 9 through 45 years of age for the prevention of anal cancer, anal precancerous or dysplastic lesions and external genital lesions (including genital warts) caused by HPV.* *GARDASIL 9 is indicated to prevent the following diseases:* • *Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58* • *Genital warts (condyloma acuminata) caused by HPV types 6 and 11* *And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:* • *Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.*	
3.	3.1 **KEYTRUDA 100mg SOLUTION FOR INFUSION** [Pembrolizumab 100mg]	➢ Indication: *Head and Neck Cancer* *KEYTRUDA, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).* *KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test.*	**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

Posology

General

Patient Selection for Single-Agent Treatment of Non-Small Cell Lung Carcinoma, Head and Neck Cancer or Urothelial Carcinoma

Select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression in:

- *advanced 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].*

Recommended Dosing

KEYTRUDA is administered as an intravenous infusion over 30 minutes every 3 weeks.

The recommended dose of KEYTRUDA is:

- *200 mg for **head and neck cancer**, urothelial carcinoma, classical Hodgkin Lymphoma or previously untreated NSCLC as monotherapy.*
- *200 mg for **head and neck cancer** or NSCLC in combination therapy.*
- *2 mg/kg for melanoma or previously treated NSCLC as monotherapy.*

*When administering KEYTRUDA as part of a **combination with chemotherapy**, KEYTRUDA should be administered first. See also the prescribing information for the chemotherapy agents administered in combination.*

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.

4.	4.1 **Tecentriq 60mg/ml concentrate for solution for infusion** [Atezolizumab 60mg/ml]	➢ Indication: <u>*Non-small cell lung cancer*</u> *Tecentriq, in combination with Avastin, paclitaxel and carboplatin, is indicated for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations.* ➢ Posology: *Tecentriq combination therapy* *Please also refer to the full prescribing information for the combination product.* *1L Non-Squamous NSCLC* *Tecentriq in combination with Avastin, paclitaxel, and carboplatin* *During the induction phase, the recommended dose of Tecentriq is 1200 mg administered by intravenous (IV) infusion, followed by Avastin, paclitaxel, and then carboplatin every 3 weeks for four or six cycles.* *The induction phase is followed by a maintenance phase without chemotherapy in which 1200 mg Tecentriq followed by Avastin, is administered by IV infusion every 3 weeks.*	**Roche (Malaysia) Sdn. Bhd.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.
5.	5.1 **Kadcyla 100 mg powder for concentrate for solution for infusion** [Trastuzumab Emtansine 100 mg/vial 5.2 **Kadcyla 160 mg powder for concentrate for solution for infusion** [Trastuzumab Emtansine 160 mg/vial]	➢ Indication: *Early Breast Cancer (EBC)* *Kadcyla, as a single agent, is indicated for the adjuvant treatment of adult patients with HER2-positive early breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy.*	**Roche (Malaysia) Sdn. Bhd.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor

6.

6.1 **Lenvima 4 mg Hard Capsules**
[Lenvatinib mesilate 4.90 mg (equivalent to lenvatinib 4 mg)]

6.2 **Lenvima 10 mg Hard Capsules**
[Lenvatinib mesilate 12.25 mg (equivalent to lenvatinib 10 mg)]

- Indication:

LENVIMA, in combination with pembrolizumab, is indicated for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy and are not candidates for curative surgery or radiation. This indication is approved based on tumor response rate and durability of response (see section 11.1). Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

- Posology:

Endometrial Carcinoma
The recommended dosage of LENVIMA is 20 mg orally once daily, in combination with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks, until unacceptable toxicity or disease progression. Refer to the pembrolizumab prescribing information for recommended pembrolizumab dosing information.

Table 5 Dose modifications from recommended lenvatinib daily dose in Endometrial Carcinoma

Dose level	*Daily dose*	*Number of capsules*
Recommended daily dose	*20 mg orally once daily*	*Two 10 mg capsules*
First dose reduction	*14 mg orally once daily*	*One 10 mg capsule plus one 4 mg capsule*
Second dose reduction	*10 mg orally once daily*	*One 10 mg capsule*

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Third dose reduction	*8 mg orally once daily*	*Two 4 mg capsules*

When administering LENVIMA in combination with pembrolizumab for the treatment of endometrial carcinoma, interrupt one or both drugs or dose reduce LENVIMA as appropriate. No dose reductions are recommended for pembrolizumab. Withhold or discontinue pembrolizumab in accordance with the instructions in the pembrolizumab prescribing information.

Patients with hepatic impairment
In RCC or endometrial carcinoma, no data with the combination therapy is available in patients with hepatic impairment. No adjustment of starting dose of the combination is required on the basis of hepatic function in patients with mild (Child Pugh A) or moderate (Child Pugh B) hepatic impairment. In patients with severe (Child Pugh C) hepatic impairment, the recommended starting dose of lenvatinib is 10 mg taken once daily in combination of everolimus (recommended in the everolimus SmPC) taken once daily for RCC and 10mg once daily for endometrial carcinoma. Further dose adjustments may be necessary on the basis of individual tolerability. The combination therapy should be used in patients with severe hepatic impairment only if the anticipated benefit exceeds the risk.

Patients with renal impairment
In the DTC, RCC and endometrial carcinoma patients, no adjustment of starting dose is required on the basis of renal function in patients with mild or moderate renal impairment. In patients with severe renal impairment, the recommended starting dose for DTC is 14 mg, for RCC is 10 mg of lenvatinib with 5 mg of everolimus and for endometrial carcinoma is 10mg taken once daily. Further dose adjustments may be necessary based on individual tolerability. Patients with end-stage renal disease were not studied, therefore the use of lenvatinib in these patients is not

		recommended.	
7.	7.1 **Risperdal 1mg Tablet** [Risperidone 1mg] 7.2 **Risperdal 2mg Tablet** [Risperidone 2mg] 7.3 **Risperdal 3mg Tablet** [Risperidone 3mg] 7.4 **Risperdal Oral Solution 1mg/mL** [Risperidone 1mg/ml]	➢ Indication: *RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders.* ➢ Posology: *<u>Manic episodes in bipolar disorder</u>* *Adults* *RISPERDAL® should be administered on a once daily schedule, starting with 2 mg risperidone. Dosage adjustments, if indicated, should occur at intervals of not less than 24 hours and in dosage increments of 1 mg per day. Risperidone can be administered in flexible doses over a range of 1 to 6 mg per day to optimise each patient's level of efficacy and tolerability. Daily doses over 6 mg risperidone have not been investigated in patients with manic episodes.* *As with all symptomatic treatments, the continued use of RISPERDAL® must be evaluated and justified on an ongoing basis.* *Elderly* *A starting dose of 0.5 mg twice daily is recommended. This dosage can be individually adjusted with 0.5 mg twice daily increments to 1 to 2 mg twice daily. Since clinical experience in elderly is limited, caution should be exercised.* *Paediatric population* *Risperidone is not recommended for use in children below age 18 with bipolar mania due to a lack of data on efficacy.*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor

8.	8.1 **Abilify Maintena 400 mg powder and solvent for prolonged-release suspension for injection** [Aripiprazole Monohydrate 475mg]	➢ Indication: *Bipolar I Disorder* *Abilify Maintena is indicated for the maintenance monotherapy treatment of bipolar I disorder in adult patients.*	**LUNDBECK MALAYSIA SDN. BHD.** A-05-01, Oasis Square Jalan PJU 1A/7A Ara Damansara, 47301 Petaling Jaya, Selangor
9.	9.1 **Lipiodol Ultra Fluide 10ml** [Iodine 4.8g/10ml]	➢ Indication: *In interventional radiology* *- Visualisation, localisation and vectorisation during Trans-Arterial Chemo-Embolisation (TACE) of hepatocellular carcinoma at intermediate stage, in adults.* ➢ Posology: *Trans-Arterial Chemo-Embolisation of hepatocellular carcinoma:* *The administration is by selective intra-arterial catheterism of the hepatic artery. The procedure should be performed within a typical interventional radiology setting with the appropriate equipment. The dose of LIPIODOL ULTRA-FLUIDE depends on the extent of the lesion, but should usually not exceed a total dose of 15 mL in adults.* *LIPIODOL ULTRA-FLUIDE can be mixed with anticancer drugs such as cisplatin, doxorubicin, epirubicin and mitomycin. Instructions and precautions for use of the anticancer drugs must be strictly followed.* *Instructions for preparation of the mixture of LIPIODOL ULTRA-FLUIDE with an anticancer drug:* *- Prepare two syringes large enough to contain the total volume of mixture. The first syringe contains the anticancer drug solution, the second syringe contains LIPIODOL ULTRA-FLUIDE.* - *Connect the two syringes to a 3-way stopcock.* - *Perform 15 to 20 back and forth movements between the two syringes to obtain a homogeneous mixture. It is*	**MEDI-DIAGNOSTIC SOLUTIONS (M) SDN. BHD.** No. 23-1 & 23-2, Jalan PJU 7/16A Mutiara Damansara, 47800 Petaling Jaya, Selangor

		recommended to start by pushing the syringe with the anticancer drug first. - *The mixture is to be prepared at the time of use and must be used promptly after preparation (within 3 hours). If necessary during the interventional radiology procedure, the mixture can be re-homogenised as described above.* - *When the adequate mixture is obtained, use a 1 to 3 mL syringe to inject in the micro-catheter.* - *The procedure can be repeated every 4 to 8 weeks according to tumour response and patient conditions.* *Paediatric population* *The efficacy and safety of the use of LIPIODOL ULTRA-FLUIDE for Trans-Arterial Chemo-Embolisation of hepatocellular carcinoma have not been established in children.* *Elderly* *The product must be administered with special care in patients over 65 years of age with underlying diseases of the cardiovascular, respiratory or nervous systems.*	
10	10.1 **Mozobil 20 mg/ml solution for Injection** [Plerixafor 20mg/ml]	➢ Indication: *Paediatric patients (1 to less than 18 years)* *Mozobil is indicated in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children with lymphoma or solid malignant tumours, either:* • *pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or* • *who previously failed to collect sufficient haematopoietic stem cells.*	**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

		➢ Posology: *<u>Paediatric (1 to less than 18 years)</u>* *The recommended daily dose of plerixafor by subcutaneous injection (SC) is:* • *0.24 mg/kg of body weight.* *Each vial of plerixafor is filled to deliver 1.2 ml of 20 mg/ml plerixafor aqueous solution for injection containing 24 mg of plerixafor. Plerixafor has to be drawn up into a syringe size type which should be selected according to the weight of the patient.* *For low weight patients, up to 45 kg of body weight, 1 ml syringes for use in infant patients can be used. This type of syringe has major graduations for 0.1 ml and minor graduations for 0.01 ml and therefore is suitable to administer plerixafor, at a dose of 240 µg/kg, to paediatric patients of at least 9 kg body weight. For patients of more than 45 kg, a1 ml or 2 ml syringe with graduations that allow a volume to 0.1 ml to be measured can be used.* *<u>Special populations</u>* *Paediatric population* *The safety and efficacy of Mozobil in children (1 to less than 18 years) were studied in an open label, multicenter, controlled study.*	