Maklumat tambahan indikasi
Year 2017
Products Approved For Additional Indication (DCA 313 – 4 July 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Gardasil 9 [Human Papillomavirus 9-valent Vaccine, Recombinant]** [Each dose of 0.5 ml contains Human Papillomavirus type: 1. 6 L1 30 mcg 2. 11 L1 40 mcg 3. 16 L1 60 mcg 4. 18 L1 40 mcg 5. 31 L1 20 mcg 6. 33 L1 20 mcg 7. 45 L1 20 mcg 8. 52 L1 20 mcg 9. 58 L1 20 mcg]	➢ Posology: ***DOSAGE AND ADMINISTRATION*** ***General*** ***Dosage*** *GARDASIL 9 should be administered intramuscularly as 3 separate 0.5-ml doses according to the following schedule:* *First dose : at elected date.* *Second dose: 2 months after the first dose.* *Third dose : 6 months after the first dose.* *Individuals are encouraged to adhere to the 0, 2, and 6 months vaccination schedule. However, in clinical studies, efficacy has been demonstrated in individuals who have received all 3 doses within a 1-year period. The second dose should be administered at least 1 month after the first dose, and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period.* *Alternatively, in individuals 9 through 14 years of age, GARDASIL 9 can be administered according to a 2-dose schedule; the second dose should be administered between 5 and 13 months after the first dose. If the second vaccine dose is administered earlier than 5 months after the first dose, a third dose should always be administered.* *The use of GARDASIL 9 should be in accordance with official recommendations.* ***Method of administration*** *GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.* *GARDASIL 9 must not be injected intravascularly. Neither subcutaneous nor intradermal administration has been studied. These methods of administration are not recommended.* *The vaccine should be used as supplied; no dilution or reconstitution is*	**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

		necessary. The full recommended dose of the vaccine should be used. *Shake well before use through agitation immediately before administration is necessary to maintain suspension of the vaccine.* *After thorough agitation, GARDASIL 9 is a white, cloudy liquid. Parenteral drug products should be inspected visually for particulate matters and discoloration prior to administration. Discard the product if particulates are present or if it appears discoloured.* *The prefilled syringe is for single use only and should not be used for more than one individual. Inject the entire contents of the syringe.* ***Administration of GARDASIL 9 in Individuals Who Have Been Previously Vaccinated with GARDASIL*** *It is recommended that individuals who receive a first dose of GARDASIL 9 complete the vaccination course with GARDASIL 9.* *Studies using a mixed regimen (interchangeability) of HPV vaccines were not performed for GARDASIL 9.* *If the decision is made to administer GARDASIL 9 after receiving 3 doses of GARDASIL, there should be an interval of at least 12 months between completion of vaccination with GARDASIL and the start of vaccination with GARDASIL 9.*	

2.	2.1 **Keytruda 100mg Solution for Infusion** [Pembrolizumab 100mg]	➢ Indication <u>*Head and Neck Cancer*</u> *KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.* *This indication is approved based on the overall response rate (ORR) and durability of response. Continued approval for this indication may be contingent upon the verification of the results from the confirmatory clinical studies.* ➢ Posology: <u>*Recommended Dosing*</u> *KEYTRUDA is administered as an intravenous infusion over 30 minutes every 3 weeks.* *The recommended dose of KEYTRUDA is:* • *200mg for head and neck cancer or previously untreated NSCLC* • *2mg/kg for melanoma or previously treated NSCLC* *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.*	**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

3.	3.1 **Vytorin 10/10 mg Tablet** [Ezetimibe 10 mg, Simvastatin 10 mg] 3.2 **Vytorin 10/20 mg Tablet** [Ezetimibe 10 mg, Simvastatin 20 mg] 3.2 **Vytorin 10/40 mg Tablet** [Ezetimibe 10 mg, Simvastatin 40 mg] 3.2 **Vytorin 10/80 mg Tablet** [Ezetimibe 10 mg, Simvastatin 80 mg]	➢ Indication: *Prevention of Cardiovascular Events* *VYTORIN is indicated to reduce the risk of cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, hospitalization for unstable angina, or need for revascularization), in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not.* ➢ Posology: *Patients with Coronary Heart Disease* *In the cardiovascular events risk reduction study (IMPROVE-IT), the starting dose was 10/40 mg once a day in the evening. The 10/80-mg dose is only recommended when the benefits are expected to outweigh the potential risks.*	**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
4.	4.1 **EZETROL 10MG** [Ezetimibe 10 mg]	➢ Indication: *Prevention of Cardiovascular Events* *EZETROL, administered with a statin, is indicated to reduce the risk of cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, hospitalization for unstable angina, or need for revascularization), in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS).* ➢ Posology: *Use in Patients with Coronary Heart Disease* *Combination Therapy with a Statin* *For incremental cardiovascular event reduction in patients with coronary heart disease, EZETROL 10 mg may be administered with a statin with proven cardiovascular benefit.*	**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