Maklumat tambahan indikasi
Year 2017
Products Approved For Additional Indication (DCA 318 – 27 November 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Volibris 5 mg film coated tablet** [Ambrisentan 5 mg] 1.2 **Volibris 10 mg film coated tablet** [Ambrisentan 10 mg]	➢ Indication: *Volibris is indicated for treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment. Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease.* ➢ Posology: *Ambrisentan monotherapy* *Volibris is to be taken orally to begin at a dose of 5 mg once daily and may be increased to 10 mg daily depending upon clinical response and tolerability.* *Ambrisentan in combination with tadalafil* *When used in combination with tadalafil, Volibris should be titrated to 10 mg once daily.* *In the AMBITION study, patients received 5 mg ambrisentan daily for the first 8 weeks before up titrating to 10 mg, dependent on tolerability. When used in combination with tadalafil, patients were initiated with 5 mg ambrisentan and 20 mg tadalafil. Dependent on tolerability the dose of tadalafil was increased to 40 mg after 4 weeks and the dose of ambrisentan was increased to 10 mg after 8 weeks. More than 90% of patients achieved this. Doses could also be decreased depending on tolerability.*	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Level 6, Quill 9 112, Jalan Semangat 46300 Petaling Jaya, Selangor
2.	2.1 **Jardiance 10mg film coated tablets** [Empagliflozin 10 mg] 2.2 **Jardiance 25mg film coated tablets** [Empagliflozin 25 mg]	➢ Indication: *Prevention of cardiovascular death* *Jardiance is indicated in patients with type 2 diabetes mellitus and established cardiovascular disease to reduce the risk of cardiovascular death.* *To prevent cardiovascular deaths, Jardiance should be used in*	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15 Wisma UOA Damansara II No 6, Jalan Changkat

		conjunction with other measures to reduce cardiovascular risk in line with the current standard of care. ➢ Posology: *Monotherapy and add-on combination* *The recommended starting dose is 10 mg empagliflozin once daily for monotherapy and add-on combination therapy with other glucose-lowering medicinal products including insulin. In patients tolerating empagliflozin 10 mg once daily who have an eGFR ≥45 ml/min/1.73 m2 and need tighter glycaemic control, the dose can be increased to 25 mg once daily. The maximum daily dose is 25 mg.* *When empagliflozin is used in combination with a sulphonylurea or with insulin, a lower dose of the sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia.* *Special populations* *Patients with renal impairment* *Due to the mechanism of action, the efficacy of empagliflozin is dependent on renal function. Jardiance should not be initiated in patients with eGFR persistently below 45 ml/min/1.73 m2. No dose adjustment is required for patients with an eGFR ≥ 45 ml/min/1.73 m2 or CrCl ≥ 45 ml/min.* *Jardiance should be discontinued if eGFR is persistently ≤ 45 ml/min/1.73 m2 or CrCl ≤ 45 ml/min.* *Empagliflozin should not be used in patients with end stage renal disease (ESRD) or in patients on dialysis as it is not expected to be effective in these patients.*	Semantan Damansara Heights 50490 Kuala Lumpur
3.	3.1 **Humira Solution for Injection in Pre-filled Syringe 40mg/0.4ml** [Adalimumab 40mg/0.4ml] 3.2 **Humira Solution for Injection in Pre-filled Syringe 40mg/0.4ml** [Adalimumab 40mg/0.4ml]	➢ Indication: <u>*Uveitis*</u> *Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.*	**ABBVIE SDN BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort 47410 Petaling Jaya, Selangor

	3.3 **Humira Solution For Injection** [Adalimumab 40mg/0.8ml]	➢ Posology: <u>*Uveitis*</u> *The recommended dose of Humira for adult patients with uveitis is an initial dose of 80mg, followed by 40mg given every other week starting one week after the initial dose. There is limited experience in the initiation of treatment with Humira alone. Treatment with Humira can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Humira.*	
4.	4.1 **VARIVAX REFRIGERATED VARICELLA VIRUS VACCINE, LIVE (OKA/MERCK)** [Each 0.5 mL of vaccine contains a minimum of 1350 PFU varicella virus vaccine Oka/Merck strain]	➢ Posology: *FOR SUBCUTANEOUS ADMINISTRATION* *Do not inject intravenously.* *Children 12 months to 12 years of age should receive a single 0.5 mL dose administered subcutaneously. If a second dose is administered, there should be a minimum interval of 3 months between doses.* *Adolescents and adults 13 years of age and older should receive a 0.5 mL dose administered subcutaneously at elected date and a second 0.5 mL dose 4 to 8 weeks later.* *The outer aspect of the upper arm (deltoid region) is the preferred site of injection.*	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22 The Ascent, Paradigm Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor
5.	5.1 **PRIORIX-TETRA POWDER AND DILUENT FOR SOLUTION FOR INJECTION** After reconstitution, 1 dose (0.5 ml) contains: Live attenuated measles virus[1] (Schwarz strain) — not less than $10^{3.0}$ CCID50 [3] Live attenuated mumps virus[1] (RIT 4385 strain, derived from Jeryl Lynn strain) — not less than $10^{4.4}$ CCID50 [3] Live attenuated rubella virus[2] (Wistar RA 27/3 strain) — not less than $10^{3.0}$ CCID50 [3]	➢ Indication: *Priorix-Tetra is indicated for active immunisation in subjects from the age of 9 months up to 12 years of age inclusive against measles, mumps, rubella and varicella.* ➢ Posology: *Primary immunisation consists of one dose of vaccine.*	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Level 6, Quill 9 112, Jalan Semangat 46300 Petaling Jaya, Selangor

Live attenuated varicella virus[2] (OKA strain)	not less than $10^{3.3}$ PFU[4]

[1] produced in chick embryo cells
[2] produced in human diploid (MRC-5) cells
[3] Cell Culture Infective Dose 50%
[4] Plaque forming units

If official recommendations call for additional doses of measles, mumps, rubella and/or varicella, Priorix-Tetra can be used for these doses.

The dose interval should preferably be between 6 weeks and 3 months. In no circumstances should this interval be less than 4 weeks.

MMR-varicella vaccination at the age of 9-11 months should be considered in certain cases in infants at increased risk of measles. However it should then be borne in mind that infants in their first year of life may not respond sufficiently to the components of the vaccine due to the possible interference with maternal antibodies. A second dose of Priorix-Tetra should be given three months after the first dose.

Method of administration

The vaccine is to be injected subcutaneously (SC) or intramuscularly (IM) in the deltoid region or in the anterolateral area of the thigh.

The vaccine should be administered subcutaneously in subjects with bleeding disorders (e.g. thrombocytopenia or any coagulation disorder).

For instructions on reconstitution of the medicinal product before administration see "Instructions for Use/Handling".