Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 341 – 5 December 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Hizentra 200 mg/ml Solution for Subcutaneous Injection** [Human immunoglobulin 200 mg/ml]	➢ Indication: *Immunomodulatory therapy* • *Hizentra is indicated for the treatment of patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy after stabilization with intravenously administered immunoglobulins (IVIg).* ➢ Posology: *Immunomodulatory therapy in CIDP patients* *The therapy with Hizentra is initiated 1 week after the last IVIg infusion. The recommended subcutaneous dose is 0.2 to 0.4 g/kg bw per week. The weekly dose can be divided into smaller doses and administered by desired number of times per week. For dosing every two weeks, double the weekly Hizentra dose. The dose may need to be adapted to achieve the desired clinical response. Patient's individual clinical response should be the primary consideration in dose adjustment.* *If CIDP symptoms worsen on 0.4 g/kg bw per week, re-initiating therapy with IVIg should be considered, while discontinuing Hizentra.* *Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy.*	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/ 26A, Kelana Jaya 47301 Petaling Jaya, Selangor

2.	2.1 **Lynparza 100 mg Film-Coated Tablets** [Olaparib 100mg] 2.2 **Lynparza 150 mg Film-Coated Tablets** [Olaparib 150mg]	➢ Indication: *Lynparza is indicated as monotherapy for the:* *maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.* ➢ Posology: *Treatment with Lynparza should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.* *Detection of BRCA1/2 mutations* *Before Lynparza treatment is initiated for first-line maintenance treatment of high-grade epithelial ovarian cancer (EOC), fallopian tube cancer (FTC) or primary peritoneal cancer (PPC), patients must have confirmation of deleterious or suspected deleterious germline and/or somatic mutations in the breast cancer susceptibility genes (BRCA) 1 or 2 using a validated test.* *Genetic counselling for patients tested for mutations in BRCA1/2 genes should be performed according to local regulations.* *Posology* *Lynparza is available as 100 mg and 150 mg tablets.* *The recommended dose of Lynparza is 300 mg (two 150 mg tablets) taken twice daily, equivalent to a total daily dose of 600 mg. The 100 mg tablet is available for dose reduction.* *Patients with platinum-sensitive relapsed (PSR) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy should start treatment with Lynparza no later than 8 weeks after completion of their final dose of the*	**AstraZeneca Sdn. Bhd.** Level 11 & 12, Nucleus Tower, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor

		platinum‑containing regimen. *Duration of treatment* *First-line maintenance treatment of BRCA-mutated advanced ovarian cancer:* *Patients can continue treatment until radiological disease progression, unacceptable toxicity or for up to 2 years if there is no radiological evidence of disease after 2 years of treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating physician can derive further benefit from continuous treatment, can be treated beyond 2 years.* *Dose adjustments for adverse reactions* *Treatment may be interrupted to manage adverse reactions such as nausea, vomiting, diarrhoea, and anaemia and dose reduction can be considered.* *The recommended dose reduction is to 250 mg (one 150 mg tablet and one 100 mg tablet) twice daily (equivalent to a total daily dose of 500 mg).* *If a further dose reduction is required, then reduction to 200 mg (two 100 mg tablets) twice daily (equivalent to a total daily dose of 400 mg) is recommended.* *Dose adjustments for co-administration with CYP3A inhibitors* *Concomitant use of strong or moderate CYP3A inhibitors is not recommended and alternative agents should be considered. If a strong CYP3A inhibitor must be co‑administered, the recommended Lynparza dose reduction is to 100 mg (one 100 mg tablet) taken twice daily (equivalent to a total daily dose of 200 mg). If a moderate CYP3A inhibitor must be co‑administered, the recommended Lynparza dose reduction is to 150 mg (one 150 mg tablet) taken twice daily (equivalent to a total daily dose of 300 mg).*	

3.	3.1 **Ikervis 1mg/mL eye drops, emulsion** [Ciclosporin 1mg/mL]	➢ Indication: *Treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age through adolescence.* ➢ Posology: *Children from 4 years of age through adolescence* *The recommended dose is one drop of IKERVIS 4 times a day (morning, mid-day, afternoon and evening) to be applied to each affected eye. Response to Verneal Keratoconjunctivitis (VKC) treatment should be re-assessed at 4 months, where a decision can be made to continue treatment. The treatment can be maintained at the recommended dose or decreased to one drop twice daily once adequate control of signs and symptoms is achieved. Treatment should be discontinued after signs and symptoms are resolved, and reinitiated upon their recurrence.* *Efficacy and safety of IKERVIS in VKC has not been studied beyond 12 months.* *If a dose is missed, treatment should be continued on the next instillation as normal. Patients should be advised not to instill more than one drop for each instillation in the affected eye(s).* *Children below 4 years* *There is no relevant use of IKERVIS in the treatment of severe VKC in children below 4 years.* *Adults* *The effect of IKERVIS in VKC has not been studied in patients above 18 years of age.* *Patients with renal or hepatic impairment* *The effect of IKERVIS in VKC has not been studied in patients with renal or hepatic impairment. However, no special dose adjustment is needed in these populations*	**SANTEN PHARMA MALAYSIA SDN. BHD.** Unit #23A-10, Q Sentral No. 2A, Jalan Stesen Sentral 2 Kuala Lumpur Sentral 50470 Kuala Lumpur

4.	4.1 **Flutiform 50 microgram/5 microgram per actuation pressurised inhalation, suspension** [Fluticasone propionate 50mcg & formoterol fumarate dihydrate 5mcg]	➢ Indication: *Flutiform 50 microgram /5 microgram inhaler is indicated in adults, adolescents and children aged 5 years and above.* ➢ Posology: *Recommended dose for adults, adolescents and children aged 5 years and above:* *Flutiform 50 microgram/5 microgram inhaler - two inhalations (puffs) twice daily normally taken in the morning and in the evening.* *Children under 5 years:* *Experience in children under the age of 5 years is limited.* *Flutiform inhaler in any strength is not recommended for use in children less than 5 years of age; Flutiform inhaler should not be used in this young age group.*	**MUNDIPHARMA PHARMACEUTICALS SDN. BHD.** A-3-01 Level 3, Block A PJ8, No. 23 Jalan Barat, Seksyen 8 46050 Petaling Jaya, Selangor
5.	5.1 **Foster Nexthaler 100 micrograms/6 micrograms per dose inhalation powder** [Beclomethasone dipropionate 100 mcg (equivalent to delivered dose of 81.9 mcg of beclometasone propionate anhydrous) & formoterol fumarate 6 mcg (equivalent to delivered dose of 5.0 micrograms of formoterol fumarate dihyrate)]	➢ Indication: *<u>Chronic obstructive pulmonary disease (COPD)</u>* *Symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.* ➢ Posology: *Dose recommendations for adults 18 years and above:* *Two inhalations twice daily.*	**ORIENT EUROPHARMA (M) SDN. BHD.** E-08, Garden Shoppe One City, Jalan USJ 25/1C 47650 Subang Jaya, Selangor

6.	6.1 **Relvar Ellipta 100/25 micrograms inhalation powder, pre-dispensed** [Fluticasone Furoate 100mcg + Vilanterol 25mcg (40 mcg of vilanterol trifenatate is equivalent to 25 mcg of vilanterol)] 6.2 **Relvar Ellipta 200/25 micrograms inhalation powder, pre-dispensed** [Fluticasone Furoate 200mcg + Vilanterol 25mcg (40 mcg of vilanterol trifenatate is equivalent to 25 mcg of vilanterol)]	➢ Indication: *Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 18 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate:* • *patients already adequately controlled on both inhaled corticosteroid and long-acting beta2-agonist.*	**GLAXOSMITHKLINE PHARMACEUTICAL SDN BHD** Level 6, Quill 9, No 112, Jalan Semangat, 46300 Petaling Jaya, Selangor