Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 372 – 12 Mei 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	RINVOQ 15mg Extended Release Film Coated Tablets [Upadacitinib Hemihydrate 15.4 mg (corresponds to 15 mg of upadacitinib on an anhydrous basis)]	**INDICATION :** Atopic dermatitis RINVOQ is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. **POSOLOGY :** Atopic dermatitis Adults The recommended dose of upadacitinib is 15 mg or 30 mg once daily based on individual patient presentation. • A dose of 30 mg once daily may be appropriate for patients with high disease burden. • A dose of 30 mg once daily may be appropriate for patients with an inadequate response to 15 mg once daily. • The lowest effective dose for maintenance should be considered. For patients ≥ 65 years of age, the recommended dose is 15 mg once daily. Adolescents (from 12 to 17 years of age) The recommended dose of upadacitinib is 15 mg once daily for adolescents weighing at least 40 kg. RINVOQ has not been studied in adolescents weighing less than 40 kg. Concomitant topical therapies	**ABBVIE SDN. BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Upadacitinib can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used for sensitive areas such as the face, neck, and intertriginous and genital areas. <u>Dose initiation</u> Treatment should not be initiated in patients with an absolute lymphocyte count (ALC) that is < 0.5 x 10^9 cells/L, an absolute neutrophil count (ANC) that is < 1 x 10^9 cells/L or who have haemoglobin (Hb) levels that are < 8 g/dL.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Xtandi 40mg Soft Capsules [Enzalutamide 40mg]	**INDICATION :** the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT) (see section 5.1) **POSOLOGY** : Same as approved posology with the addition of: Paediatric population There is no relevant use of enzalutamide in the paediatric population in the indication of treatment of patients with CRPC and mHSPC.	**ASTELLAS PHARMA MALAYSIA SDN. BHD.** Suite 18.05, Level 18, Centrepoint North Tower, Mid Valley City, Lingkaran Syed Putra, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Cetraxal Plus Ear Drops Solution [Ciprofloxacin 0.3% Fluocinolone Acetonide 0.025%]	**INDICATION:** Cetraxal Plus is indicated in adults and in children aged 6 months and older for the following infections: • Acute otitis externa (AOE) • Acute otitis media in patients with tympanostomy tubes (AOMT) caused by ciprofloxacin susceptible microorganisms. Consideration should be given to official guidance on the appropriate use of antibacterial agents. **POSOLOGY** : Adults and elderly population Acute otitis externa and acute otitis media with tympanostomy tubes: Instil 6-8 drops into the affected external ear canal every 12 hours for 7 days. No overall differences in safety and effectiveness have been observed between elderly and other adult patients. Paediatric population The dosage in children aged 6 months and older is the same as for adults for both indications. Renal/ hepatic impairment No dosage adjustment is deemed necessary. Method of administration Auricular use. Precautions to be taken before handling or administering the medicinal product The solution should be warmed before its use, by holding the bottle in the hand for several minutes. This will avoid the discomfort that may result from the instillation of a cold solution	**HYPHENS PHARMA SDN. BHD.** L1-10 & L1-11, PJ Mid Town, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		into the ear canal. The patient should lie with the affected ear upward and then the drops should be instilled pulling several times on the auricle. For patients with acute otitis media with tympanostomy tubes, the tragus should be pumped 4 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for around 1 minute to facilitate penetration of the drops into the ear. Repeat, if necessary, for the opposite ear. To prevent contamination of the dropper tip in order to limit bacterial risks, care should be taken not to touch the auricle or the external ear canal and surrounding areas, or other surfaces with the dropper tip of the bottle. Keep the bottle tightly closed when not in use. Keep the bottle until the completion of the treatment.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Entresto 50mg Film-coated Tablets [Sacubitril/Valsartan (corresponds to 50mg LCZ696 free anhydrous acid (sacubitril 24.3mg and valsartan 25.7mg)] Entresto 100mg Film-coated Tablets [Sacubitril/Valsartan (corresponds to 100mg LCZ696 free anhydrous acid (sacubitril 48.6mg and valsartan 51.4mg)] Entresto 200mg Film-coated Tablets [Sacubitril/Valsartan (corresponds to 200mg LCZ696 free anhydrous acid (sacubitril 97.2mg and valsartan 102.8mg)]	**INDICATION :** ENTRESTO is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat. Entresto is administered in combination with other heart failure therapies (e.g. beta blockers, diuretics and mineralocorticoid antagonists) as appropriate, in place of an ACE inhibitor or ARB.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	PFZ Methotrexate Tablet 2.5mg [Methotrexate 2.5mg]	**INDICATION :** Rheumatoid Arthritis **POSOLOGY** : Rheumatoid arthritis (RA) 1. Single oral doses of 7.5 to 20 mg once weekly. 2. Divided oral doses of 2.5 to 7.5 mg every 12 hours for three doses, repeated weekly. A total weekly dose 20 mg should not be exceeded. Once optimal clinical response has been achieved, dosing should be reduced to the lowest possible effective dose. The optimal duration of therapy is unknown; limited data from long term studies indicate that the initial clinical improvement is maintained for at least 2 years with continued therapy.	**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.