Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 398, 4 Julai 2024

Products approved for additional indication (DCA 398 – 4 July 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	ELIDEL 1% CREAM [Pimecrolimus 10mg/g]	**INDICATION :** Elidel® 1 % cream is indicated for the treatment of mild to moderate atopic dermatitis for patients 3 months of age and older where treatment with topical corticosteroids is either inadvisable or not possible, this may include: • Intolerance to topical corticosteroids • Lack of effect of topical corticosteroids • Use on the face and neck where prolonged intermittent treatment with topical corticosteroids may be inappropriate **POSOLOGY :** Elidel should be initiated by physicians with experience in the diagnosis and treatment of atopic dermatitis. Elidel can be used in the short term for the treatment of the signs and symptoms of atopic eczema and intermittently in the long term for the prevention of progression to flares. Elidel treatment should begin at the first appearance of signs and symptoms of atopic dermatitis. Elidel should only be applied to areas affected with atopic dermatitis. Pimecrolimus should be used for as short period as possible during flares of disease. The patient or caregiver should stop using pimecrolimus when signs and symptoms resolve. Treatment should be intermittent, short-term and not continuous. If no improvement occurs after 6 weeks, or in case of disease exacerbation, treatment should be stopped. The diagnosis of atopic dermatitis should be re-evaluated and further therapeutic options considered.	**MYLAN HEALTHCARE SDN. BHD.** 15-03 & 15-04, Level 15, Imazium, No. 8, Jalan SS 21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Adults Apply a thin layer of Elidel to the affected skin twice daily and rub in gently and completely. Each affected region of the skin should be treated with pimecrolimus until clearance occurs and then treatment should be discontinued. Elidel may be used on all skin areas, including the head and face, neck and intertriginous areas, except on mucous membranes. Elidel should not be applied under occlusion. In the long-term management of atopic dermatitis (eczema), Elidel treatment should begin at first appearance of signs and symptoms of atopic dermatitis to prevent flares of the disease. Elidel should be used twice daily. Emollients can be applied immediately after using Elidel. **Paediatric population** For infants (3-23 months), children (2-11 years) and adolescents (12-17 years) the posology and method of administration are the same as for adults. **Elderly patients** Atopic dermatitis (eczema) is rarely observed in patients aged 65 and over. Clinical studies with Elidel did not include a sufficient number of patients in this age range to determine whether they respond differently from younger patients. **Method of administration** Elidel should be applied thinly to the affected areas twice daily.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	RINVOQ 15mg Extended Release Film Coated Tablets [Upadacitinib Hemihydrate 15.4mg (Corresponds to 15 mg of upadacitinib)] RINVOQ 30 mg extended-release film coated tablets [Upadacitinib Hemihydrate 30.7mg (Corresponds to 30 mg of upadacitinib)]	**INDICATION:** <u>Crohn's disease</u> RINVOQ® is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent. **POSOLOGY:** Crohn's disease Induction The recommended induction dose of RINVOQ® is 45 mg once daily for 12 weeks. For patients who have not achieved adequate therapeutic benefit after the initial 12-week induction, prolonged induction for an additional 12 weeks with a dose of 30 mg once daily may be considered. For these patients, upadacitinib should be discontinued if there is no evidence of therapeutic benefit after 24 weeks of treatment. Maintenance The recommended maintenance dose of RINVOQ® 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 or those who do not show adequate therapeutic benefit with 15 mg once daily. • The lowest effective dose for maintenance should be used. For patients ≥ 65 years of age, the recommended maintenance dose is 15 mg once daily. In patients who have responded to treatment with RINVOQ®, corticosteroids may be reduced and/or discontinued in accordance with standard of care.	**ABBVIE SDN. BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Skyrizi solution for injection in pre-filled syringe 150MG/ML [Risankizumab 150 mg/mL] Skyrizi solution for injection in pre-filled pen 150MG/ML Skyrizi 75 mg solution for injection in pre-filled syringe [Risankizumab 75 mg/0.83mL]	**INDICATION :** <u>Palmoplantar Pustulosis</u> SKYRIZI is indicated for the treatment of moderate to severe palmoplantar pustulosis in adults who do not adequately respond or are intolerant to conventional therapy. **POSOLOGY :** Skyrizi is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Skyrizi is indicated. <u>Posology</u> The recommended dose is 150 mg administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter (either as two 75 mg pre-filled syringe injections or one 150 mg pre-filled pen or pre-filled syringe injection). Some plaque psoriasis patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks. Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment. Patients with palmoplantar pustulosis generally achieve a clinical response to treatment with SKYRIZI within 28 weeks of treatment initiation. If no response to treatment is achieved within 28 weeks, carefully reconsider whether to continue the treatment protocol with SKYRIZI.	**ABBVIE SDN. BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Nucala 100mg/ml Solution for Injection in pre-filled syringe (Safety Syringe) Nucala 100mg/ml Solution for Injection in pre-filled pen (Autoinjector) [Mepolizumab 100mg/ml]	**INDICATION :** Eosinophilic Granulomatosis with Polyangiitis (EGPA) NUCALA is indicated as add-on treatment for relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA) in adult patients aged 18 years and over. **POSOLOGY :** Eosinophilic Granulomatosis with Polyangiitis (EGPA) Injection sites should be at least 5 cm apart. Adults The recommended dose is 300 mg of NUCALA administered by subcutaneous (SC) injection once every 4 weeks. Children and adolescents under 18 years of age The safety and efficacy of NUCALA has not been tested in adolescents and children with EGPA who are under 18 years of age.	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Hz.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.