Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 393, 8 Februari 2024

Products approved for additional indication (DCA 393, 8 Februari 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	RINVOQ 15mg Extended Release Film Coated Tablets [Upadacitinib Hemihydrate (Corresponds to 15 mg of upadacitinib)] RINVOQ 30mg Extended Release Film Coated Tablets [Upadacitinib Hemihydrate (Corresponds to 30 mg of upadacitinib)]	**INDICATION :** *Ulcerative Colitis* *RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.* **POSOLOGY :** Ulcerative Colitis Induction The recommended induction dose of RINVOQ is 45 mg once daily for 8 weeks. For patients who do not achieve adequate therapeutic benefit by week 8, RINVOQ 45 mg once daily may be continued for an additional 8 weeks (see Undesirable effects and Pharmacodynamic properties sections). RINVOQ should be discontinued in any patient who shows no evidence of therapeutic benefit by week 16. 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 some patients, such as those with high disease burden or requiring 16 week induction treatment. • A dose of 30 mg once daily may be appropriate for patients who do not show adequate therapeutic benefit to 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.	**ABBVIE SDN. BHD.** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 393, 8 Februari 2024

Products approved for additional indication (DCA 393, 8 Februari 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		In patients who have responded to treatment with RINVOQ, corticosteroids may be reduced and/or discontinued in accordance with standard of care. <u>Interactions</u> For patients with ulcerative colitis receiving strong inhibitors of cytochrome P450 (CYP) 3A4 (e.g., ketoconazole, clarithromycin), the recommended induction dose is 30 mg once daily and the recommended maintenance dose is 15 mg once daily (see section Interaction with other medicinal products and other forms of interaction) <u>Special Populations</u> Elderly Ulcerative colitis For ulcerative colitis, doses higher than 15 mg once daily for maintenance therapy are not recommended in patients 65 years of age and older (see undesirable effects section). The safety and efficacy of upadacitinib in patients 75 years of age and older have not yet been established. Renal Impairment No dose adjustment is required in patients with mild or moderate renal impairment. There are limited data on the use of upadacitinib in subjects with severe renal impairment (see Pharmacokinetic properties section). Upadacitinib should be used with caution in patients with severe renal impairment. The use of upadacitinib has not been studied in subjects with end stage renal disease and is therefore not recommended for use in these patients. For patients with severe renal impairment, the following dose adjustments are recommended:	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 393, 8 Februari 2024

Products approved for additional indication (DCA 393, 8 Februari 2024)

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>

Table 2. Recommended Dose for Severe Renal Impairment [a]

<table>
<tr><td rowspan="4">Severe renal impairment</td><td>Indication</td><td>Recommended once daily dose</td></tr>
<tr><td>Rheumatoid arthritis, psoriatic arthritis, atopic dermatitis</td><td>15 mg</td></tr>
<tr><td rowspan="2">Ulcerative Colitis</td><td>Induction: 30 mg</td></tr>
<tr><td>Maintenance: 15 mg</td></tr>
<tr><td colspan="3">[a]estimated glomerular filtration rate (eGFR) 15 to < 30 ml/min/1.73m^2</td></tr>
</table>

Paediatric population

The safety and efficacy of RINVOQ in adolescents weighing < 40 kg and in children aged 0 to less than 12 years have not yet been established. No data are available.

The safety and efficacy of RINVOQ® in children and adolescents with rheumatoid arthritis, psoriatic arthritis and ulcerative colitis aged 0 to less than 18 years have not yet been established. No data are available.

</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 393, 8 Februari 2024

Products approved for additional indication (DCA 393, 8 Februari 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	HEMLIBRA 30MG/ML SOLUTION FOR INJECTION [Emicizumab 30mg/mL] HEMLIBRA 150MG/ML SOLUTION FOR INJECTION [Emicizumab 150mg/mL]	**INDICATION :** Hemlibra is indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency): • with factor VIII inhibitors • without factor VIII inhibitors who have: - severe disease (FVIII <1%) - moderate disease (FVIII ≥ 1% and ≤ 5%) with severe bleeding phenotypes Hemlibra can be used in all age groups. **POSOLOGY :** Treatment should be initiated under the supervision of a physician experienced in the treatment of haemophilia and/or bleeding disorders. Posology Treatment (including routine prophylaxis) with bypassing agents (e.g. aPCC and rFVIIa) should be discontinued the day before starting Hemlibra therapy. Factor VIII (FVIII) prophylaxis may be continued for the first 7 days of Hemlibra treatment. The recommended dose is 3 mg/kg once weekly for the first 4 weeks (loading dose), followed by a maintenance dose from week 5 of either 1.5 mg/kg once weekly, 3 mg/kg every two weeks, or 6 mg/kg every four weeks, all doses administered as a subcutaneous injection. The loading dose regimen is the same, irrespective of the maintenance dose regimen. The maintenance dose regimen should be selected based on physician and patient/caregiver dosing regimen preference to support adherence.	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 393, 8 Februari 2024

Products approved for additional indication (DCA 393, 8 Februari 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		The patient dose (in mg) and volume (in mL) should be calculated as follows: • Loading dose (3 mg/kg) once weekly for the first 4 weeks: Patient bodyweight (kg) x dose (3 mg/kg) = total amount (mg) of emicizumab to be administered. • Followed by a maintenance dose from week 5, of either 1.5 mg/kg once weekly, 3 mg/kg every two weeks or 6 mg/kg every four weeks: Patient bodyweight (kg) x dose (1.5; 3 or 6 mg/kg) = total amount (mg) of emicizumab to be administered. The total volume of Hemlibra to be injected subcutaneously is calculated as follows: Total amount (mg) of emicizumab to be administered ÷ vial concentration (mg/mL) = total volume of Hemlibra (mL) to be injected. Different Hemlibra concentrations (30 mg/mL and 150 mg/mL) should not be combined in the same syringe when making up the total volume to be administered. A volume greater than 2 mL per injection should not be administered.	