Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 371 – 7 April 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Olumiant 2mg Film-Coated Tablets [Baricitinib 2mg] Olumiant 4mg Film-Coated Tablets [Baricitinib 4mg]	**INDICATION :** COVID-19 This is conditional approval for use of baricitinib to treat COVID-19 in hospitalized adults and pediatric patients 10 years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). **POSOLOGY :** COVID-19 The recommended dose of baricitinib in adults and pediatric patients 10 years of age and older is 4 mg once daily for 14 days or until hospital discharge, whichever occurs first. Dosage adjustments are recommended for laboratory abnormalities, including renal impairment (see Table 1b). The optimal duration of treatment is unknown. Treatment initiation • COVID-19: There is limited information on the use of baricitinib in patients with ALC< 0.2 x 10^9 cells/L, ANC< 1 x 10^9 cells/L, or haemoglobin < 8 g/dL. • <u>Patient Selection</u> ▪ Evaluate baseline eGFR, liver enzymes, and complete blood count to determine treatment suitability and dose. Monitor closely patients with abnormal baseline and post-baseline laboratory values. See Table 1b for dosage adjustments for patients with laboratory abnormalities.	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		• Baricitinib is not recommended for: ▪ Patients who are on dialysis, have end-stage renal disease (ESRD, EGFR <15 mL/min/1.73 m^2), or have acute kidney injury ▪ Patients with known active tuberculosis • <u>Adult Patients</u> ▪ The recommended dosage in adults with eGFR ≥60 mL/min/1.73 m^2 is 4 mg once daily for 14 days of total treatment or until hospital discharge, whichever is first. See Table 1b for dosage adjustments for patients with laboratory abnormalities. ▪ Dosage adjustments in patients with renal or hepatic impairment are recommended. ▪ Dosage adjustments due to drug interactions are recommended. ▪ In hospitalized patients with COVID-19, prophylaxis for venous thromboembolism (VTE) is recommended unless contraindicated. Co-administration with OAT3 inhibitors Strong OAT3 Inhibitors: Baricitinib exposure is increased when baricitinib is co-administered with strong OAT3 inhibitors, such as probenecid. In patients taking strong OAT3 inhibitors, such as probenecid, reduce the recommended dose as follows: • If the recommended dose is 4 mg once daily, reduce dose to 2 mg once daily. <u>Special populations</u> Renal impairment • COVID-19: There are limited data for baricitinib in patients with severe renal impairment.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)

		• Baricitinib is not recommended for patients who are on dialysis, have ESRD, or have acute kidney injury.
		• See Table 1b for treatment modifications for patients with laboratory abnormalities.
		  ○ Baricitinib should only be used in adults and pediatric patients 10 years of age and older with eGFR 15 to < 30 mL/min/1.73 m^2 if the potential benefit outweighs the potential risk.
		Hepatic impairment
		• COVID-19: Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib should only be used in patients with severe hepatic impairment if the potential benefit outweighs the potential risk. It is not known if dosage adjustment is needed in patients with severe hepatic impairment.
		See Table 1b for dosage adjustments for patients with abnormal laboratory values.
		Elderly
		• COVID-19: No dose adjustment is required in patients ≥ 75 years. The clinical experience in patients ≥ 75 years is limited.
		Paediatric population
		• COVID-19: Limited data informing baricitinib dosing in pediatric patients comes from ongoing clinical trials for other uses. Based on the available information, treatment for COVID-19 for pediatric patients under this EUA is as follows:
		  ○ The recommended dosage for patients 10 years of age and older is 4 mg once daily for 14 days of total treatment or until hospital discharge, whichever is first.
		  ○ Dosage adjustments in patients with renal or hepatic impairment are recommended.	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Method of administration</u> Alternative administration for COVID-19 For patients who are unable to swallow whole tablets, alternate administration may be considered: • Oral dispersion • Gastrostomy tube (G tube) • Nasogastric tube (NG tube)	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Pulmicort Respules 0.25mg/ml [Budesonide 0.25 mg/ml] Pulmicort Respules 0.5mg/ml [Budesonide 0.5 mg/ml]	**INDICATION :** PULMICORT RESPULES can be used in patients with exacerbations of chronic obstructive pulmonary disease (COPD) in persons without signs of acute respiratory insufficiency. **POSOLOGY** : **EXACERBATIONS OF COPD:** Patients should be treated with daily doses of 4 to 8 mg of PULMICORT RESPULES, divided into two to four administrations, until clinical improvement is achieved, but for no longer than 10 days. The use of nebulised budesonide has not been evaluated in clinical trials in patients with an exacerbation of COPD with respiratory failure requiring invasive mechanical ventilation or admission to intensive care unit. Time to effect in exacerbations of COPD Following inhaled administration of PULMICORT RESPULES for the treatment of exacerbations of COPD the time to symptom improvement is comparable to administration of systemic corticosteroids.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	COVILO Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated [Each dose (0.5 mL) contains 3.9-10.4 units (4µg/dose protein content) of inactivated SARS-CoV-2 virus (19nCoV-CDC-Tan-HB02 strain) (Vero cell) antigen]	**POSOLOGY** : Immunization Regimen and Dosage: Two dose regimen at an interval of 21~28 days, each dose is 0.5mL **A booster dose (0.5ml) may be administered at least 3-6 months after the second dose when the potential benefits outweigh any potential risks**. **The decision when and for whom to implement a booster dose of the vaccine should be made based on available vaccine effectiveness data, taking into account limited safety data (see clinical section)** Instructions for Use: Before use, carefully check the vaccine container, label, appearance and expiration date. If there are cracks, spots, stains, scratches, blurred label on the container, vaccine expired, or abnormal appearance observed, the vaccine shall not be used. The vaccine should be thoroughly mixed by shaking the vial before use and use immediately after opening. The recommended administration is through intramuscular route, the injection into a muscle will be preferably performed in the upper part of the arm.	**DUOPHARMA (M) SDN. BHD.** Lot 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor.

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>4.</td><td>ACTEMRA 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION

[Tocilizumab 20mg/ml]</td><td>
INDICATION :

<u>Coronavirus disease 2019 (COVID-19)</u>
Tocilizumab is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

POSOLOGY :

<u>COVID-19</u>

The recommended dose of tocilizumab for treatment of adult patients with COVID-19 is a single 60-minute infusion of 8 mg/kg in patients who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of tocilizumab 8 mg/kg may be administered at least 8 hours after the initial infusion.

For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended.

Administration of Actemra is not recommended in patients with COVID-19 who have any of the following laboratory abnormalities:
<table>
<tr><th>Laboratory test type</th><th>Laboratory value</th><th>Action</th></tr>
<tr><td>Liver enzyme</td><td>≥ 10 x ULN</td><td rowspan="3">Administration of Actemra is not recommended</td></tr>
<tr><td>Absolute neutrophil count</td><td>< 1 x 10^9 / L</td></tr>
<tr><td>Platelet count</td><td>< 50 x 10^3 / µL</td></tr>
</table>
</td><td>ROCHE (MALAYSIA) SDN. BHD.
Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway,
47500 Subang Jaya, Selangor.</td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	Influvac Tetra, suspension for injection in pre-filled syringe [1 dose (0.5 ml) contains a combination of influenza virus surface antigens (inactivated) of the following strains: • A/Victoria/2570/2019(H1N1)pdm09-like strain (A/Victoria/2570/2019, IVR-215)* • A/Cambodia/e0826360/2020 (H3N2)-like strain (A/Cambodia/e0826360/2020, IVR-224)* • B/Washington/02/2019-like strain (B/Washington/02/2019, wild type)* • B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type)* *15µg haemagglutinin/dose]	**INDICATION :** Active immunisation for the prevention of influenza caused by influenza virus, types A and B. Influvac® Tetra is indicated in adults and children from 6 months of age. The use of Influvac® Tetra should be based on official recommendations. **POSOLOGY** : Adults: 0.5 ml. Paediatric population Children from 6 months to 17 years of age: 0.5 ml. Children less than 9 years of age, who have not previously been vaccinated with a seasonal influenza vaccine: a second dose of 0.5 ml should be given after an interval of at least 4 weeks. Infants less than 6 months of age: the safety and efficacy of Influvac® Tetra have not been established. <u>Method of Administration</u> Immunisation should be carried out by intramuscular or deep subcutaneous injection. The preferred sites for intramuscular injection are the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults. Precautions to be taken before handling or administrating the medicinal product. For instructions for preparation of the medicinal product before administration, see section 5.6.	**ABBOTT LABORATORIES (M) SDN. BHD.** 27-02, Level 27, Imazium, No. 8, Jalan SS 21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.