Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 358 – 4 Jun 2021)

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
1.	Tagrisso Film-Coated Tablet 40mg [Osimertinib 40 mg] Tagrisso Film-Coated Tablet 80mg [Osimertinib 80 mg]	**INDICATION :** TAGRISSO (osimertinib) is indicated for: • the adjuvant therapy after tumour resection in adult patients with non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. **POSOLOGY:** When considering the use of TAGRISSO, EGFR mutation status should be determined using a validated test method for: • exon 19 deletions or exon 21 (L858R) substitution mutations (in tumour specimens for adjuvant treatment and tumour or plasma specimens for first-line treatment) • T790M mutations (in tumour or plasma specimens following progression on or after EGFR TKI therapy). Posology The recommended dose is 80 mg osimertinib once a day. If a dose of TAGRISSO is missed, the dose should be made up unless the next dose is due within 12 hours. Treat patients in the adjuvant setting until disease recurrence, or unacceptable toxicity, or for up to 3 years. Treat patients with locally advanced or metastatic lung cancer until disease progression or unacceptable toxicity.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

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2.	Risperdal® Consta® 25 mg [Risperidone 25 mg] Risperdal® Consta® 37.5 mg [Risperidone 37.5 mg] Risperdal® Consta® 50 mg [Risperidone 50 mg]	**INDICATION :** RISPERDAL® CONSTA® is indicated as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder. **POSOLOGY:** Bipolar Disorder The recommended dose for monotherapy or adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder is 25 mg IM every 2 weeks. Some patients may benefit from a higher dose of 37.5 mg or 50 mg. Dosages above 50 mg have not been studied in this population. The physician who elects to use RISPERDAL® CONSTA® for extended periods should periodically re-evaluate the long-term risks and benefits of the drug for the individual patient. Elderly (65 years of age and older) For elderly patients treated with RISPERDAL® CONSTA®, the recommended dosage is 25 mg IM every 2 weeks. Oral RISPERDAL® (or another antipsychotic medication) should be given with the first injection of RISPERDAL® CONSTA® and should be continued for 3 weeks to ensure that adequate therapeutic plasma concentrations are maintained prior to the main release phase of risperidone from the injection site (see Pharmacokinetic Properties). *Other information for Special populations (pediatric, hepatic and renal impairment) under the posology section remains the same. Administration RISPERDAL® CONSTA® should be administered every two weeks by deep intramuscular deltoid or gluteal injection. Each injection should be administered by a health care professional using the appropriate enclosed safety needle. For deltoid administration, use the 1-inch needle alternating injections between the two arms. For gluteal administration, use the 2-inch needle alternating injections between the two buttocks. Do not administer intravenously.	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor.

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3.	Abilify Maintena 400 mg powder and solvent for prolonged-release suspension for injection [Aripiprazole Monohydrate]	**INDICATION:** Abilify Maintena is indicated for treatment of schizophrenia in adult patients stabilized with oral aripiprazole. Efficacy has been established in both acute and maintenance phases of schizophrenia.	**LUNDBECK MALAYSIA SDN. BHD.** A-05-01, Oasis Square, Jalan PJU 1A/7A, Ara Damansara, 47301 Petaling Jaya, Selangor.
4.	Xofluza Film-Coated Tablet 20mg [Baloxavir marboxil 20mg] Xofluza Film-Coated Tablet 40mg [Baloxavir marboxil 40mg]	**INDICATION:** Xofluza is indicated for post-exposure prophylaxis of influenza in persons 12 years of age and older following contact with an individual who has influenza. **POSOLOGY:** **Dosage and Administration Overview** <u>Initiate treatment with Xofluza</u> Xofluza should be taken as soon as possible after influenza symptom onset or exposure to influenza and may be taken with or without food. However, co-administration of Xofluza with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc) should be avoided. **Recommended Dosage** <u>Treatment of Acute Uncomplicated Influenza or Post-Exposure Prophylaxis in Adults and Adolescents (12 Years of Age and older)</u> Xofluza should be taken as a single dose as soon as possible and within 48 hours of influenza symptom onset for treatment of acute uncomplicated influenza or following	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

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<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Marketing Authorization Holder</th></tr>
<tr><td></td><td></td><td>contact with an individual who has influenza.

The recommended dosage of Xofluza in patients 12 years of age or older is a single weight-based dose displayed in Table 1.

Table 1 Recommended Xofluza Dosage in Adults and Adolescents (12 Years of Age and Older)
<table><tr><th>Patient Body Weight (kg)</th><th>Recommended Oral Dose</th></tr><tr><td>40 kg to less than 80 kg</td><td>Single dose of 40 mg</td></tr><tr><td>At least 80 kg</td><td>Single dose of 80 mg</td></tr></table></td><td></td></tr>
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