Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 417, 3 Februari 2026

Products approved for additional indication (DCA 417 – 3 February 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Enhertu Powder For Concentrate For Solution For Infusion 100 mg/vial [Trastuzumab Deruxtecan 100mg/ 5ml]	**INDICATION:** HER2-Low and HER2- Ultralow Metastatic Breast Cancer ENHERTU is indicated for the treatment of adult patients with unresectable or metastatic ● Hormone receptor (HR)-positive HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow [IHC 0 with membrane staining (IHC >0<1+)] breast cancer, that has progressed on one or more endocrine therapies in the metastatic setting. ● HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. **POSOLOGY:** HER2-low or HER2-ultralow breast cancer Patients treated with trastuzumab deruxtecan should have documented HER2-low tumour status, defined as a score of IHC 1+ or IHC 2+/ISH, or HER2 ultralow tumour status, described as IHC 0 with membrane staining (IHC >0<1+), as assessed by a CE-marked IVD medical device. If a CE-marked IVD is not available, the HER2 status should be assessed by an alternate validated test (see section 5.1).	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.
2.	Bilaxten 2.5 mg/mL Oral Solution [Bilastine 2.5 mg/mL]	**INDICATION:** Bilaxten 2.5 mg/mL Oral Solution Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilaxten 2.5 mg/mL Oral Solution is indicated in children aged 2 to 11 years with a body weight of at least 15 kg.	**A. MENARINI SINGAPORE PTE. LTD.** B-18-2, Level 18, The Ascent Paradigm, No.1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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<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>Bilaxten 10mg Orodispersible Tablets

[Bilastine 10mg]</td><td>
<u>Bilaxten 10mg Orodispersible Tablets</u>

Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilaxten 10mg Orodispersible Tablets is indicated in children aged <u>2</u> to 11 years with a body weight of at least <u>15 kg</u>.

POSOLOGY:
<table>
<tr><th>Bilaxten 2.5 mg/mL Oral Solution</th><th>Bilaxten 10mg Orodispersible Tablets</th></tr>
<tr><td>Paediatric population

Children <u>2</u> to 11 years of age with a body weight of at least <u>15</u> kg:

10 mg bilastine (4 mL of oral solution) once daily for the relief of symptoms of allergic rhino-conjunctivitis (seasonal allergic rhinitis and perennial allergic rhinitis) and urticaria. The oral solution should be taken one hour before or two hours after intake of food or fruit juice

Adults:

In adults and adolescents (over 12 years of age) the administration of bilastine 20 mg tablets is appropriate.</td><td>Paediatric population

Children <u>2</u> to 11 years of age with a body weight of at least <u>15</u> kg:

10 mg bilastine (1 orodispersible tablet) once daily for the relief of symptoms of allergic rhino-conjunctivitis (seasonal allergic rhinitis and perennial allergic rhinitis) and urticaria. The orodispersible tablet should be taken one hour before or two hours after intake of food or fruit juice.

In adults and adolescents (over 12 years of age) the administration of bilastine 20 mg tablets is appropriate.</td></tr>
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No.	Product [Active Ingredient]	Additional Indication		Product Registration Holder (PRH)
		Duration of treatment: For allergic rhino-conjunctivitis the treatment should be limited to the period of exposure to allergens. For seasonal allergic rhinitis treatment could be discontinued after the symptoms have resolved and reinitiated upon their reappearance. In perennial allergic rhinitis continued treatment may be proposed to the patients during the allergen exposure periods. For urticaria the duration of treatment depends on the type, duration and course of the complaints. Special populations Renal impairment: The safety and efficacy of bilastine in renally impaired children have not been established. Studies conducted in adults in special risk groups (renally impaired patients) indicate that it is not necessary to adjust the dose of bilastine in adults. Hepatic impairment: The safety and efficacy of bilastine in hepatically impaired children have not	Duration of treatment: For allergic rhino-conjunctivitis the treatment should be limited to the period of exposure to allergens. For seasonal allergic rhinitis treatment could be discontinued after the symptoms have resolved and reinitiated upon their reappearance. In perennial allergic rhinitis continued treatment may be proposed to the patients during the allergen exposure periods. For urticaria the duration of treatment depends on the type, duration and course of the complaints. Special populations Renal impairment: The safety and efficacy of bilastine in renally impaired children have not been established. Studies conducted in adults in special risk groups (renally impaired patients) indicate that it is not necessary to adjust the dose of bilastine in adults. Hepatic impairment: The safety and efficacy of bilastine in hepatically impaired children have not been established. There is no clinical experience in	

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		been established. There is no clinical experience in both adult and paediatric patients with hepatic impairment. However, since bilastine is not metabolized and is eliminated as unchanged in urine and feces, hepatic impairment is not expected to increase systemic exposure above the safety margin in adult patients. Therefore, no dosage adjustment is required in adult patients with hepatic impairment. <u>Method of administration</u> Oral use The bottle of oral solution is provided with a child-proof cap and must be opened as follows: press the plastic screw-cap downwards and simultaneously turn anti-clockwise. The oral solution is accompanied by a measuring cup for dosage with a mark of 4 mL (= 10 mg bilastine per dosing).	both adult and paediatric patients with hepatic impairment. However, since bilastine is not metabolized and is eliminated as unchanged in urine and feces, hepatic impairment is not expected to increase systemic exposure above the safety margin in adult patients. Therefore, no dosage adjustment is required in adult patients with hepatic impairment. <u>Method of administration</u> Oral use The orodispersible tablet is to be placed in the mouth where it disperses rapidly in saliva, so it can be easily swallowed. Alternatively, the orodispersible tablet may be dispersed in water before administration <u>to reduce the risk of choking or aspiration in children.</u> Grapefruit juice or any other fruit juices should not be used for dispersion.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Iclusig Film-Coated Tablet 15mg [Ponatinib Free Base (added as ponatinib HCl) 15mg] Iclusig Film-Coated Tablet 45mg [Ponatinib Free Base (added as ponatinib HCl) 45mg]	**INDICATION:** Newly diagnosed Ph+ ALL, in combination with chemotherapy. **POSOLOGY:** The recommended starting dosage of Iclusig in combination with chemotherapy is 30 mg orally once daily with a reduction to 15 mg orally once daily upon achievement of MRD-negative (≤0.01% BCR::ABL1/ABL1) CR at the end of induction. Patients with loss of MRD negativity can re-escalate the dose of Iclusig to a previously tolerated dosage of up to 30 mg orally once daily. After completion of Iclusig in combination with chemotherapy, continue treatment with Iclusig as single agent therapy until loss of response at the re-escalated dose or unacceptable toxicity (see section 5.1). For a description of dosing of agents administered in combination with Iclusig, see section 5.1. <u>Elderly patients</u> Of the 163 patients with Ph+ ALL who received Iclusig in PhALLCON, 21% were 65 years and older and 7% were 75 years and older. Overall, no differences in efficacy of Iclusig were observed between patients 65 years of age or older compared to younger patients. AOEs occurred in 21% (7/34) of patients 65 years and older and 2.3% (3/129) of patients less than 65 years of age. <u>Hepatic impairment</u> For patients with newly diagnosed Ph+ ALL, no dosage adjustment is recommended when administering Iclusig to patients with mild hepatic impairment (Child-Pugh A). Closely monitor patients with moderate or severe hepatic impairment (Child-Pugh B or C) and modify the Iclusig dosage in the event of adverse reactions (see section 4.4).	**STEWARD CROSS SDN. BHD.** No. 2, Jalan SS 13/5, 47500 Subang, Selangor.