Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 405, 4 Februari 2025

Products approved for additional indication (DCA 405 – 4 Februari 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Fycompa 2mg Film-coated Tablets [Perampanel 2 mg] Fycompa 4mg Film-coated Tablets [Perampanel 4 mg]	**INDICATION :** Fycompa (perampanel) is indicated for the adjunctive treatment of - partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older. - primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE). **POSOLOGY :** <u>Posology</u> Fycompa must be titrated, according to individual patient response, in order to optimise the balance between efficacy and tolerability. Fycompa should be taken orally once daily at bedtime. The physician should prescribe the most appropriate formulation and strength according to weight and dose. **Partial-Onset Seizures** Fycompa at doses of 4 mg/day to 12 mg/day has been shown to be effective therapy in partial- onset seizures. The following table summarises the recommended posology for adults, adolescents and children from 4 years of age. More details are provided below the table.	**EISAI (MALAYSIA) SDN. BHD.** Unit 701D, Level 7, Tower D, Uptown 5, No.5, Jalan SS21/39, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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<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>
<tr><td></td><td>Adult/adolescent (12 years and older)</td><td colspan="3">Children (4 - 11 years); weighing:</td></tr>
<tr><td></td><td></td><td>≥ 30 kg</td><td>20 - < 30 kg</td><td>< 20 kg</td></tr>
<tr><td>Recommended starting dose</td><td>2 mg/day</td><td>2 mg/day</td><td>1 mg/day</td><td>1 mg/day</td></tr>
<tr><td>Titration (incremental steps)</td><td>2 mg/day (no more frequently than weekly intervals)</td><td>2 mg/day (no more frequently than weekly intervals)</td><td>1 mg/day (no more frequently than weekly intervals)</td><td>1 mg/day (no more frequently than weekly intervals)</td></tr>
<tr><td>Recommended maintenance dose</td><td>4 - 8 mg/day</td><td>4 - 8 mg/day</td><td>4 - 6 mg/day</td><td>2 - 4 mg/day</td></tr>
<tr><td>Titration (incremental steps)</td><td>2 mg/day (no more frequently than weekly intervals)</td><td>2 mg/day (no more frequently than weekly intervals)</td><td>1 mg/day (no more frequently than weekly intervals)</td><td>0.5 mg/day (no more frequently than weekly intervals)</td></tr>
<tr><td>Recommended maximum dose</td><td>12 mg/day</td><td>12 mg/day</td><td>8 mg/day</td><td>6 mg/day</td></tr>
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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Children (from 4 to 11 years) weighing ≥ 30 kg Treatment with Fycompa should be initiated with a dose of 2 mg/day. The dose may be increased based on clinical response and tolerability by increments of 2 mg (either weekly or every 2 weeks as per half-life considerations described below) to a maintenance dose of 4 mg/day to 8 mg/day. Depending upon individual clinical response and tolerability at a dose of 8 mg/day, the dose may be increased by increments of 2 mg/day to 12 mg/day. Patients who are taking concomitant medicinal products that do not shorten the half-life of Fycompa should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of Fycompa should be titrated no more frequently than at 1-week intervals. Children (from 4 to 11 years of age) weighing 20 kg and < 30 kg Treatment with Fycompa should be initiated with a dose of 1 mg/day. The dose may be increased based on clinical response and tolerability by increments of 1 mg (either weekly or every 2 weeks as per half-life considerations described below) to a maintenance dose of 4 mg/day to 6 mg/day. Depending upon individual clinical response and tolerability at a dose of 6 mg/day, the dose may be increased by increments of 1 mg/day to 8 mg/day. Patients who are taking concomitant medicinal products that do not shorten the half-life of Fycompa should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of Fycompa should be titrated no more frequently than at 1-week intervals. Children (from 4 to 11 years of age) weighing < 20 kg Treatment with Fycompa should be initiated with a dose of 1 mg/day. The dose may be increased based on clinical response and tolerability by increments of 1 mg (either weekly or every 2 weeks as per half-life considerations described below) to a maintenance dose of 2 mg/day to 4 mg/day. Depending upon individual clinical response and tolerability at a dose of 4 mg/day, the dose may be increased by increments of 0.5 mg/day to 6 mg/day. Patients who are taking concomitant medicinal products that do not shorten the half-life of Fycompa should	

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be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of perampanel should be titrated no more frequently than at 1-week intervals.

Primary Generalised Tonic-Clonic Seizures

Fycompa at a dose up to 8 mg/day has been shown to be effective in primary generalised tonic-clonic seizures.

The following table summarises the recommended posology for adults, adolescents and children from 7 years of age. More details are provided below the table.
<table>
<tr><td></td><td rowspan="2">Adult/adolescent (12 years and older)</td><td colspan="3">Children (7 - 11 years); weighing:</td></tr>
<tr><td>≥ 30 kg</td><td>20 - < 30 kg</td><td>< 20 kg</td></tr>
<tr><td>Recommended starting dose</td><td>2 mg/day</td><td>2 mg/day</td><td>1 mg/day</td><td>1 mg/day</td></tr>
<tr><td>Titration (incremental steps)</td><td>2 mg/day (no more frequently than weekly intervals)</td><td>2 mg/day (no more frequently than weekly intervals)</td><td>1 mg/day (no more frequently than weekly intervals)</td><td>1 mg/day (no more frequently than weekly intervals)</td></tr>
<tr><td>Recommended maintenance dose</td><td>Up to 8 mg/day</td><td>4 - 8 mg/day</td><td>4 - 6 mg/day</td><td>2 - 4 mg/day</td></tr>
<tr><td>Titration (incremental</td><td>2 mg/day (no more frequently than</td><td>2 mg/day (no more frequently</td><td>1 mg/day (no more frequently</td><td>0.5 mg/day (no more frequently</td></tr>
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<tr><td>steps)</td><td>weekly intervals)</td><td>than weekly intervals)</td><td>than weekly intervals)</td><td>than weekly intervals)</td></tr>
<tr><td>Recommended maximum dose</td><td>12 mg/day</td><td>12 mg/day</td><td>8 mg/day</td><td>6 mg/day</td></tr>
</table>
Children (from 7 to 11 years) weighing ≥ 30 kg
Treatment with Fycompa should be initiated with a dose of 2 mg/day. The dose may be increased based on clinical response and tolerability by increments of 2 mg (either weekly or every 2 weeks as per half-life considerations described below) to a maintenance dose of 4 mg/day to 8 mg/day. Depending upon individual clinical response and tolerability at a dose of 8 mg/day, the dose may be increased by increments of 2 mg/day to 12 mg/day. Patients who are taking concomitant medicinal products that do not shorten the half-life of Fycompa should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of Fycompa should be titrated no more frequently than at 1-week intervals.
Children (from 7 to 11 years of age) weighing 20 kg and < 30 kg
Treatment with Fycompa should be initiated with a dose of 1 mg/day. The dose may be increased based on clinical response and tolerability by increments of 1 mg (either weekly or every 2 weeks as per half-life considerations described below) to a maintenance dose of 4 mg/day to 6 mg/day. Depending upon individual clinical response and tolerability at a dose of 6 mg/day, the dose may be increased by increments of 1 mg/day to 8 mg/day. Patients who are taking concomitant medicinal products that do not shorten the half-life of Fycompa should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of Fycompa should be titrated no more frequently than at 1-week intervals.
</td><td></td></tr>
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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Children (from 7 to 11 years of age) weighing < 20 kg Treatment with Fycompa should be initiated with a dose of 1 mg/day. The dose may be increased based on clinical response and tolerability by increments of 1 mg (either weekly or every 2 weeks as per half-life considerations described below) to a maintenance dose of 2 mg/day to 4 mg/day. Depending upon individual clinical response and tolerability at a dose of 4 mg/day, the dose may be increased by increments of 0.5 mg/day to 6 mg/day. Patients who are taking concomitant medicinal products that do not shorten the half-life of Fycompa should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of Fycompa should be titrated no more frequently than at 1-week intervals. Paediatric population The safety and efficacy of Fycompa have not yet been established in children below 4 years of age in the POS indication or in children below 7 years of age in the PGTCS indication.	

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Products approved for additional indication (DCA 405 – 4 Februari 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	BRILINTA 90MG FILM-COATED TABLET [Ticagrelor 90mg]	**POSOLOGY :** Discontinuation of ASA may be considered after 3 months in patients with ACS who have undergone a percutaneous coronary intervention (PCI) procedure and have an increased risk of bleeding. In that case, ticagrelor as single antiplatelet therapy should be continued for 9 months (see section “Special Warnings and Precautions For Use”).	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 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>3.</td><td>Ferinject® 50 mg iron/mL solution for injection/infusion

[Ferric carboxymaltose 50mg/ml]</td><td>POSOLOGY :

<u>Amendment to Table 1 in Step 1 of the approved posology, as follows:</u>

Table 1: Determination of the iron need
<table><tr><th colspan="2">Hb</th><th colspan="3">Patient body weight</th></tr><tr><th>g/dL</th><th>mmol/L</th><th>below 35 kg</th><th>35 kg to <70 kg</th><th>70 kg and above</th></tr><tr><td><10</td><td><6.2</td><td><s>500</s>30<u>-mg/kg body weight</u></td><td>1,500 mg</td><td>2,000 mg</td></tr><tr><td>10 to <14</td><td>6.2 to <8.7</td><td><s>500</s>15 <u>mg/kg body weight</u></td><td>1,000 mg</td><td>1,500 mg</td></tr><tr><td>≥14</td><td>≥8.7</td><td><s>500</s>15<u>-mg/kg body weight</u></td><td>500 mg</td><td>500 mg</td></tr></table>
<u>Addition of the following to the approved posology:</u>

Step 2: Calculation and administration of the maximum individual iron dose(s)

Children and adolescents aged 1 to 13 years

A single Ferinject administration should not exceed:

• 15 mg iron/kg body weight

• 750 mg of iron (15 mL Ferinject)

The maximum recommended cumulative dose of Ferinject is 750 mg of iron (15 mL Ferinject) per week. If the total iron need is higher, then the administration of an additional dose should be a minimum of 7 days apart from the first dose.</td><td>ZUELLIG PHARMA SDN. BHD.
No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong,
40150 Shah Alam, Selangor.</td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Children below 1 year of age The efficacy and safety of Ferinject has not been investigated in children below 1 year of age. Ferinject is therefore not recommended for use in children in this age group. **Patients with haemodialysis-dependent chronic kidney disease** In children aged 1 to 13 years with chronic kidney disease requiring haemodialysis, the efficacy and safety of Ferinject has not been investigated. Ferinject is therefore not recommended for use in children aged 1 to 13 years with chronic kidney disease requiring haemodialysis. <u>Method of administration</u> Intravenous injection In children aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight but should not exceed 750 mg of iron. Intravenous infusion In children aged 1 to 13 years, the maximum single dose is 15 mg iron/kg body weight but should not exceed 750 mg of iron.	

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Products approved for additional indication (DCA 405 – 4 Februari 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Trulicity 0.75mg solution for injection in pre-filled pen [Dulaglutide 0.75mg in 0.5ml solution] Trulicity 1.5mg solution for injection in pre-filled pen [Dulaglutide 1.5mg in 0.5ml solution]	**INDICATION :** Type 2 Diabetes Mellitus Trulicity is indicated for the treatment of patients 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindication. • in addition to other medicinal products for the treatment of diabetes. For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1. **POSOLOGY :** Adults Monotherapy The recommended dose is 0.75 mg once weekly. Add-on therapy The recommended dose is 1.5 mg once weekly. **Paediatrics** **The starting dose for paediatric patients 10 years and above is 0.75 mg once weekly.** **If needed, the dose can be increased to 1.5 mg once weekly after at least 4 weeks. The maximum dose is 1.5 mg once weekly.**	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Combination therapy</u> When Trulicity is added to existing metformin and/or pioglitazone therapy, the current dose of metformin and/or pioglitazone can be continued. When Trulicity is added to existing metformin and/or sodium-glucose co-transporter 2 inhibitor (SGLT2i) therapy, the current dose of metformin and/or SGLT2i can be continued. When it is added to existing therapy of a sulphonylurea or insulin, a reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia (see sections 4.4 and 4.8). The use of Trulicity does not require blood glucose self-monitoring. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea or insulin, particularly when Trulicity therapy is started and insulin is reduced. A stepwise approach to insulin dose reduction is recommended. <u>Missed doses</u> If a dose is missed, it should be administered as soon as possible if there are at least 3 days (72 hours) until the next scheduled dose. If less than 3 days (72 hours) remain before the next scheduled dose, the missed dose should be skipped and the next dose should be administered on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule. <u>Special population</u> Elderly No dose adjustment is required based on age (see section 5.2). Renal impairment No dose adjustment is required in patients with mild, moderate or severe renal impairment (eGFR < 90 to ≥ 15 mL/min/1.73m2).	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		There is very limited experience in patients with end stage renal disease (< 15 ml/min/1.73m2), therefore Trulicity cannot be recommended in this population (see sections 5.1 and 5.2). Hepatic impairment No dose adjustment is required in patients with hepatic impairment. Paediatric population The safety and efficacy of dulaglutide in children aged less than **10** years have not been established and no data are available (see sections 5.1 and 5.2). <u>Method of administration</u> Trulicity is to be injected subcutaneously in the abdomen, thigh or upper arm. It should not be administered intravenously or intramuscularly. The dose can be administered at any time of day, with or without meals. The day of weekly administration can be changed if necessary, as long as the last dose was administered 3 or more days (72 hours) before.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** KEYTRUDA, in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), is indicated for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy.	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.