Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 378 – 3 November 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Jardiance 10mg film coated tablets [Empagliflozin 10mg]	**INDICATION** : Heart failure Jardiance is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV).	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15, Wisma UOA Damansara II, No 6, Jalan Changkat Semantan, Damansara Heights, 50490 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	ROMIPLATE 250 µg INJECTION [Romiplostim 250 µg]	**INDICATION:** <u>Aplastic anaemia</u> Romiplate is indicated for adults with moderate to severe aplastic anaemia refractory to conventional therapies. **POSOLOGY :** <u>Posology and method of administration</u> Treatment should remain under the supervision of a physician who is experienced in the treatment of haematological diseases. <u>Posology</u> Romiplate should be administered once weekly as a subcutaneous injection. <u>Initial dose</u> <u>Aplastic anaemia</u> Usually administer an initial dose of 10 µg/kg subcutaneously as romiplostim (genetical recombination) for adults. After initiation of treatment, the dose may be adjusted based on the patient's condition, and administer once weekly. The maximum weekly dose is 20 µg/kg. <u>Dose calculation</u>	**KYOWA KIRIN MALAYSIA SDN. BHD.** Suite A501, 5th Floor, West Wing, Wisma Consplant 2, No 7 Jalan SS 16/1, 47500 Subang Jaya, Selangor.

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Initial or subsequent once weekly dose:	Weight* in kg x Dose in µg/kg = Individual patient dose in µg
Volume to administer:	Dose in µg x $\frac{1\ \text{mL}}{500\ \mu\text{g}}$ = Amount to inject in mL
Example:	75 kg patient is initiated at 1 µg/kg of romiplostim. The individual patient dose = 75 kg x 1 µg/kg = 75 µg The corresponding amount of Romiplate® solution to inject = 75 µg x $\frac{1\ \text{mL}}{500\ \mu\text{g}}$ = 0.15 mL
*Actual body weight at initiation of treatment should always be used when calculating dose of romiplostim. Future dose adjustments are based on changes in platelet counts only and made in 1 µg/kg increments (see Table below).	

<u>Dose adjustments</u>

A subject's actual body weight at initiation of therapy should be used to calculate dose.

<u>Aplastic anaemia</u>

Blood count should be measured weekly at the initial treatment phase and during the dose adjustment phase. Even if the dose has been maintained, it should be measured about once in 4 weeks.

Generally, the dose should be adjusted with increments of 5 µg/kg. Do not exceed a maximum once weekly dose of 20 µg/kg.

Dose increase should be considered in cases where platelet count has not risen (e.g. increase by ≥ 20 × 10^9 /L from baseline or increase to ≥ 10 × 10^9 /L and ≥ 100% increase from baseline with blood transfusion independence) though the same dose has been administered for 4 consecutive weeks.

Use romiplostim at the lowest dose required for treatment in accordance with the following table:

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Platelet count (x 10^9/L)	Adjustment rule
200 - 400	Reduce the dose.
> 400	Suspend treatment. Once the platelet count has fallen to 200 × 10^9/L after suspension of treatment, resume romiplostim lower dose compared to the dose prior to suspension. If the dose before suspension of treatment was 5 µg/kg or lower, and if the platelet count has fallen to 50 × 10^9/L, treatment may be resumed at the same dose as before suspension of treatment.

Reduce the dose in case where 3 blood cell lineage improvement is observed (e.g. platelet count above 50 × 10^9 /L with blood transfusion independence, hemoglobin above 10 g/dL with blood transfusion independence, and neutrophil count above 1 × 10^9 /L) for at least 8 consecutive weeks. If the improvement in 3 blood lineages has been maintained with the reduced dose for 4 weeks, further reduce the dose and consider subsequent dose reduction every 4 weeks (In the case of 5 µg/kg or lower, consider suspension of treatment). If the condition has worsened in any of the 3 blood cell lineages, consider a dose increase (if the treatment has been suspended, it may be resumed at the previous dose).

Treatment discontinuation

Aplastic anaemia

Appropriate measures such as discontinuing romiplostim should be taken in cases where none of the 3 blood lineages has improved even though the maximum weekly dose of 20 µg/kg has been administered for 8 consecutive weeks.

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3.	Tecentriq 60mg/ml Concentrate for Solution for Infusion [Atezolizumab 60mg/ml]	**INDICATION:** <u>Early-stage non-small cell lung cancer</u> Tecentriq as monotherapy is indicated as adjuvant treatment following complete resection and no progression after platinum-based adjuvant chemotherapy for adult patients with stage II to IIIA (as per 7th edition of the UICC/AJCC staging system) NSCLC whose tumours have PD-L1 expression on ≥ 50% of tumour cells. **POSOLOGY:** The recommended dose of Tecentriq in monotherapy or combination therapy is: • 840 mg administered by IV infusion every 2 weeks, or • 1200 mg administered by IV infusion every 3 weeks, or • 1680 mg administered by IV infusion every 4 weeks. Tecentriq monotherapy	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

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		Early-stage NSCLC, 1L metastatic NSCLC Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test (see section 3.1.2 Clinical / Efficacy Studies). Tecentriq combination therapy For the use of Tecentriq in combination therapy, please also refer to the full prescribing information for the combination product. Tecentriq should be administered prior to IV combination therapy if given on the same day. 1L Non-Squamous metastatic NSCLC Tecentriq in combination with Avastin, paclitaxel, and carboplatin During the induction phase, Tecentriq is administered according to its dosing schedules by intravenous (IV) infusion, and Avastin, paclitaxel, and carboplatin are administered every 3 weeks for four or six cycles. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion, and Avastin is administered every 3 weeks. Tecentriq in combination with nab-paclitaxel and carboplatin: During the induction phase, Tecentriq is administered according to its dosing schedules by IV infusion, and nab-paclitaxel and carboplatin are administered every 3 weeks for four or six cycles. For each 21-day cycle, nab-paclitaxel and carboplatin are administered on day 1. In addition, nab-paclitaxel is administered on days 8 and 15. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedule. 1L ES-SCLC Tecentriq in combination with carboplatin and etoposide During the induction phase, Tecentriq is administered according to its dosing schedules by IV infusion, and carboplatin, and etoposide are administered by IV infusion on every three weeks for four cycles. Carboplatin and etoposide are administered on day 1 of each cycle,	

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		and etoposide is also administered on days 2 and 3. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion. 1L TNBC Tecentriq in combination with nab-paclitaxel Tecentriq is administered according to its dosing schedules by IV infusion and 100 mg/m^2 nab-paclitaxel is administered on days 1, 8 and 15 during each 28-day cycle. Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test. HCC Tecentriq in combination with Avastin Tecentriq is administered according to its dosing schedules by IV infusion, and Avastin 15 mg/kg is administered every 3 weeks. Duration of Treatment Patients are treated with Tecentriq until loss of clinical benefit or unacceptable toxicity. 1L TNBC Patients are treated with Tecentriq until disease progression or unacceptable toxicity. <u>Early-stage NSCLC</u> <u>Patients are treated with Tecentriq for 1 year unless there is disease recurrence or unacceptable toxicity.</u>	