Maklumat tambahan indikasi
Year 2018
Products Approved For Additional Indication (DCA 322 – 2 April 2018)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Invega 3 mg Extended Release Tablets** [Paliperidone 3 mg] 1.2 **Invega 6mg Extended Release Tablets** [Paliperidone 6 mg] 1.3 **Invega 9 mg Extended Release Tablets** [Paliperidone 9 mg] 1.4 **Invega 12 mg Extended Release Tablets** [Paliperidone 12 mg]	➢ Indication: *Invega is indicated for the treatment of schizophrenia in adolescents 15 years and older, including acute treatment and recurrence prevention.* ➢ Posology: *Adolescents population* *Schizophrenia: The recommended starting dose of Invega for the treatment of schizophrenia in adolescents 15 – 17 years old is 3 mg once daily, administered in the morning.* *Adolescents weighing < 51 kg: the maximum recommended daily dose of Invega is 6 mg.* *Adolescents weighing ≥ 51 kg: the maximum recommended daily dose of Invega is 12 mg.* *Dosage adjustment, if indicated, should occur only after clinical reassessment based on the individual need of the patient. When dose increases are indicated, increments of 3 mg/day are recommended and generally should occur at intervals of 5 days or more. The safety and efficacy of Invega in the treatment of schizophrenia in adolescents between 12 and 14 years old has not been established. Currently available data are described in section Undesirable effects and Pharmacodynamic properties but no recommendation on a posology can be made. There is no relevant use of Invega in children aged less than 12 years.*	**Johnson & Johnson Sdn Bhd** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor

2.	2.1 **Faslodex Solution for Injection 250mg/5ml** [Fulvestrant 250mg/5ml]	➢ Indication: *Faslodex is indicated for the treatment of estrogen receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy.*	**AstraZeneca Sdn. Bhd.** Level 12, Surian Tower, 1 Jalan PJU 7/3, Mutiara Damansara, 47810 Petaling Jaya, Selangor, Malaysia
3.	3.1 **Visanne 2mg Tablet** [Dienogest 2 mg]	➢ Posology: <u>*Paediatric population:*</u> *Visanne is not indicated in children prior to menarche. The safety and efficacy of Visanne was investigated in an uncontrolled clinical trial over 12 months in 111 adolescent women (12 - <18) with clinically suspected or confirmed endometriosis.* *The use of Visanne in adolescent patients over a treatment period of 12 months was associated with a mean decrease in Bone Mineral Density (BMD) in the lumbar spine of 1.2%. After cessation of treatment, BMD increased towards pre-treatment levels over a period of 6 months in a subset of patients with decreased BMD (mean change from baseline -0.6%).* *Loss of BMD is of particular concern during adolescence and early adulthood, a critical period of bone accretion. It is unknown if BMD decrease in this population will reduce peak bone mass and increase the risk for fracture in later life.* *Therefore the treating physician should weigh the benefits of Visanne against the possible risks of use in each individual adolescent patient.*	**Bayer Co. (Malaysia) Sdn. Bhd.** B-19-1 & B-19-2, The Ascent Paradigm, No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor
4.	4.1 **Revolade Film-coated Tablet 25mg** [Eltrombopag olamine 31.9mg equivalent to 25mg of eltrombopag free acid]	➢ Indication: *Revolade is indicated in adult patients with acquired severe aplastic anemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for hematopoietic stem cell transplantation.*	**Novartis Corporation (Malaysia) Sdn. Bhd.** Level 22, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200

	4.2 **Revolade Film-coated Tablet 50mg** [Eltrombopag olamine 63.8mg equivalent to 50mg of eltrombopag free acid]	➢ Posology: <u>*Severe Aplastic Anemia*</u> *Initial dose regimen* *Eltrombopag should be initiated at a dose of 50 mg once daily. For patients of East Asian ancestry or those with hepatic impairment, eltrombopag should be initiated at a reduced dose of 25 mg once daily. The treatment should not be initiated when the patients have existing cytogenetic abnormalities of chromosome 7.* *Monitoring and dose adjustment* *Haematological response requires dose titration, generally up to 150 mg, and may take up to 16 weeks after starting eltrombopag. The dose of eltrombopag should be adjusted in 50 mg increments every 2 weeks as necessary to achieve the target platelet count ≥ 50,000/µl. For patients taking 25 mg once daily, the dose should be increased to 50 mg daily before increasing the dose amount by 50 mg. A dose of 150 mg daily must not be exceeded. Clinical haematology and liver tests should be monitored regularly throughout therapy with eltrombopag and the dosage regimen of eltrombopag modified based on platelet counts as outlined in Table 3.* *Table 3 Dose adjustments of eltrombopag in patients with severe aplastic anemia* **Platelet** / **Dose adjustment or response** < 50,000/µl following at least 2 weeks of therapy — Increase daily dose by 50 mg to a maximum of 150 mg/day. For patients taking 25 mg once daily, increase the dose to 50 mg daily before increasing the dose amount by 50 mg. ≥ 50,000/µl to ≤ 150,000/µl — Use lowest dose of eltrombopag to maintain platelet counts. > 150,000/µl — Decrease the daily dose by 50 mg.	Petaling Jaya, Selangor.

to ≤ 250,000/µl	Wait 2 weeks to assess the effects of this and any subsequent dose adjustments.
> 250,000/µl	Stop eltrombopag; for at least one week. Once the platelet count is ≤100,000/µl, reinitiate therapy at a daily dose reduced by 50 mg.

Tapering for tri-lineage (white blood cells, red blood cells, and platelets) responders

For patients who achieve tri-lineage response, including transfusion independence, lasting at least 8 weeks: the dose of eltrombopag may be reduced by 50%.

If counts remain stable after 8 weeks at the reduced dose, then eltrombopag must be discontinued and blood counts monitored. If platelet counts drop to < 30,000/µl, haemoglobin to < 9 g/dL or ANC < 0.5 x 10^9/L, eltrombopag may be reinitiated at the previous effective dose.

Discontinuation

If no hematological response has occurred after 16 weeks of therapy with eltrombopag, therapy should be discontinued. If new cytogenetic abnormalities are detected, it must be evaluated whether continuation of eltrombopag is appropriate. Excessive platelet count responses (as outlined in Table 3) or important liver test abnormalities also necessitate discontinuation of eltrombopag.