Maklumat tambahan indikasi
Year 2018
Products Approved For Additional Indication (DCA 328 – 15 November 2018)

<table>
<tr><th>NO</th><th>PRODUCT
(ACTIVE INGREDIENT)</th><th>ADDITIONAL INDICATION</th><th>MARKETING AUTHORIZATION HOLDER</th></tr>
<tr>
<td>1.</td>
<td>1.1 Viekirax 12.5mg/ 75mg/ 50mg Film-Coated Tablets
[Ombitasvir 12.5 mg/ Paritaprevir 75mg/ Ritonavir 50mg]</td>
<td>➢ Posology:

The recommended oral dose of Viekirax is two 12.5 mg / 75 mg / 50 mg tablets once daily with food. Viekirax should be used in combination with other medicinal products for the treatment of HCV (see Table 1).

Table 1. Recommended co-administered medicinal product(s) and treatment duration for Viekirax by patient population
<table>
<tr><th>Patient population</th><th>Treatment*</th><th>Duration</th></tr>
<tr><td>Genotype 1b, without cirrhosis or with compensated cirrhosis</td><td>Viekirax + dasabuvir</td><td>12 weeks</td></tr>
<tr><td>Genotype 1a, without cirrhosis</td><td>Viekirax + dasabuvir + ribavirin*</td><td>12 weeks</td></tr>
<tr><td>Genotype 1a, with compensated cirrhosis</td><td>Viekirax + dasabuvir + ribavirin*</td><td>**12 weeks</td></tr>
<tr><td>Genotype 4, without cirrhosis or with compensated</td><td>Viekirax + ribavirin***</td><td>12 weeks</td></tr>
<tr><td colspan="3">*Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.
**24 weeks of Viekirax + dasabuvir + ribavirin therapy is recommended for patients with genotype 1a-infection with cirrhosis who have had a previous null response to interferon (IFN) and ribavirin.
*** Viekirax (ombitasvir/paritaprevir/ ritonavir) tablets with ribavirin is indicated for the treatment of adults with genotype 4 chronic hepatitis C virus infection, including those with compensated cirrhosis, who are either treatment naïve or previously treated with peginterferon and ribavirin.</td></tr>
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</td>
<td>ABBVIE SDN. BHD.
9th Floor Menara Lien Hoe
No. 8 Persiaran Tropicana
Tropicana Golf and Country Resort
47410 Petaling Jaya, Selangor</td>
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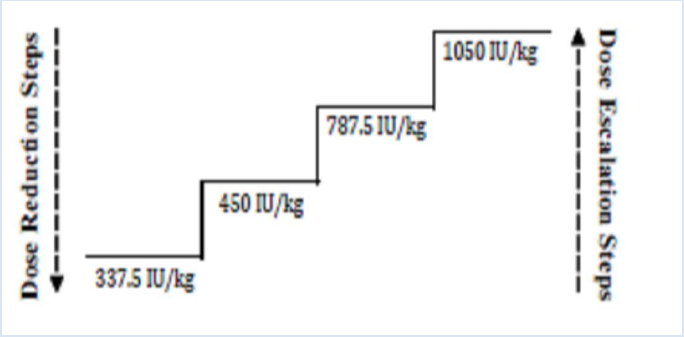
</table>

2.	2.1 **Tagrisso Film-Coated Tablet 40mg** [Osimertinib 40 mg] 2.2 **Tagrisso Film-Coated Tablet 80mg** [Osimertinib 80 mg]	➢ Indication: *TAGRISSO (osimertinib) is indicated for:* *- the first-line treatment of adult patients with locally advanced or metastatic 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 in tumour or plasma specimens should be determined using a validated test method (see section 4.4) for:* *- exon 19 deletions or exon 21 (L858R) substitution mutations (for first-line treatment)* *- T790M mutations (following progression on or after EGFR TKI therapy).*	**ASTRAZENECA SDN. BHD.** Level 12, Surian Tower 1 Jalan PJU 7/3 Mutiara Damansara 47810 Petaling Jaya, Selangor
3.	3.1 **IMBRUVICA 140MG CAPSULES** [Ibrutinib 140 mg]	➢ Indication: *IMBRUVICA as a single agent is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) (see section 5.1)*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor
4.	4.1 **Eprex Prefilled Syringe 40000IU/ML** [Epoetin Alfa 40000IU/ML] 4.2 **Eprex Prefilled Syringe 10000IU/ML** [Epoetin Alfa 10000IU/ML] 4.3 **Eprex Prefilled Syringe 4000IU/0.4ML** [Epoetin Alfa 40000IU/ML]	➢ Indication: *Eprexis indicated for the treatment of anemia (hemoglobin concentration of ≤ 10 g/dL) in adults with low- or intermediate-1-risk myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/mL).* ➢ Posology: *4.2.7 Adult Patients with low- or intermediate-1-risk MDS*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor

	4.4 **Eprex Prefilled Syringe 2000IU/0.5ML** [Epoetin Alfa 2000IU/ML]	*The subcutaneous route of administration should be used.* *Eprex should be administered to low- or intermediate-1- risk MDS patients with anemia (e.g. hemoglobin concentration ≤ 10 g/dL (6.2 mmol/L)).* *The recommended starting dose is Eprex450 IU/kg (maximum total dose is 40000 IU) administered subcutaneously once every week.* *It is recommended that response be assessed at week 8. If no erythroid response is achieved after 8 weeks according to IWG 2006 criteria (see section 5.1- Pharmacodynamic properties - Clinical efficacy and safety), and the hemoglobin concentration is below 11 g/dL (6.8 mmol/L), the dose should be increased from 450 IU/kg once every week to 1050 IU/kg once every week (maximum dose is 80000 IU per week). If the patient loses response or haemoglobin concentration drops by ≥1 g/dL upon dose reduction the dose should be increased by one dosing step. A minimum of 4 weeks should elapse between dose increases.* *Appropriate dose adjustments should be made to maintain hemoglobin concentrations within the target range of 10 g/dL to 12 g/dL (6.2 to 7.5 mmol/L). See diagram below for guidelines for stepwise dose adjustment. Eprex should be withheld or the dose reduced when the hemoglobin concentration exceeds 12 g/dL (7.5 mmol/L). Upon dose reduction, if hemoglobin concentration drops ≥1 g/dL the dose should be increased.Once the haemoglobin level is <11 g/dL the dose can be restarted on the same dosing step or one dosing step down based on physician judgement. Decreasing the dose by one dosing step should be considered if there is a rapid increase in haemoglobin (> 2 g/dL over 4 weeks).*	

		 *A sustained hemoglobin concentration of greater than 12 g/dL (7.5 mmol/L) should be avoided.*	
5.	5.1 **ACTEMRA 162MG/ 0.9ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE** [Tocilizumab 162mg/ 0.9ml]	➢ Indication: <u>*Polyarticular Juvenile Idiopathic Arthritis (pJIA)*</u> *Tocilizumab in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX.* *Tocilizumab can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.* ➢ Posology: *General* *For patients with pJIA, tocilizumab is administered as a SC injection.* <u>*Polyarticular Juvenile Idiopathic Arthritis (pJIA)*</u> *A change in dose should only be based on a consistent change in the patient's body weight over time. Tocilizumab can be used alone or in combination with MTX.*	**ROCHE (MALAYSIA) SDN BHD** Level 21, The Pinnacle, Persiaran Lagoon Bandar Sunway 47500 Subang Jaya, Selangor

		Subcutaneous Dosing Regimen: *The recommended dose of SC tocilizumab for patients with pJIA is:* *• 162 mg once every three weeks for patients below 30 kg,* *• 162 mg once every two weeks for patients ≥ 30 kg* *Dose Modification Recommendations for pJIA:* *Dose reduction of tocilizumab has not been studied in the pJIA population.* *Dose interruptions of tocilizumab for laboratory abnormalities are recommended in patients with pJIA and are similar to what is outlined above for patients with RA (also see section 2.4.4 Laboratory Tests). If appropriate, concomitant methotrexate and/or other medications should be dose modified or stopped and tocilizumab dosing interrupted until the clinical situation has been evaluated. In pJIA, the decision to discontinue tocilizumab for a laboratory abnormality should be based upon the medical assessment of the individual patient.* *2.2.1 Special Dosage Instructions* *Children: The safety and efficacy of tocilizumab in children with conditions other than pJIA have not been established. Paediatric patients below the age of 2 years old have not been established. Elderly: No dose adjustment is required in elderly patients aged 65 years and older.* *Renal impairment: No dose adjustment is required in patients with mild or moderate renal impairment (see section 3.2.5 Pharmacokinetics in Special Populations). Tocilizumab has not been studied in patients with severe renal impairment.* *Hepatic impairment: The safety and efficacy of tocilizumab has not been studied in patients with hepatic impairment (see section 2.4.1 Warnings and Precautions, General).*	