Maklumat tambahan indikasi untuk upload pada laman web
Year 2014
Products Approved For Additional Indication (DCA 272 – 23 January 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **BOTOX (BOTULINUM TOXIN TYPE A) IM INJECTION** [Clostridium Botulinum Toxin Type A 100 units/vial]	➢ Indication: *Botox is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication.* ➢ Posology: *Route of Administration:* *Intradetrusor use for bladder dysfunction only.* *Posology:* *Patients should not have a urinary tract infection prior to treatment. Prophylactic antibiotics should be administered 1-3 days pre-treatment, on the treatment day, and 1-3 days post-treatment.* *It is generally recommended that patients discontinue anti-platelet therapy at least three days before the injection procedure. Patients on anti-coagulant therapy need to be managed appropriately to decrease the risk of bleeding.* *An intravesical instillation of diluted local anaesthetics with or without sedation may be used prior to injection, per local site practice. If a local anaesthetics instillation is performed, the bladder should be drained and irrigated with sterile saline before injection.* *The recommended dose is 100 Units of Botox. The recommended dilution is 100 Units/10 mL with 0.9% non-preserved saline solution. Dispose of any unused saline.* *Reconstituted Botox (100 Units/10 mL) is injected into the detrusor muscle via a flexible or rigid cystoscope, avoiding the trigone. The bladder should be instilled with enough saline to achieve*	**ALLERGAN MALAYSIA SDN. BHD.** Level 5-02, Block A, PJ8 No.23, Jalan Barat, Seksyen 8 46050 Petaling Jaya, Selangor

		adequate visualization for the injections, but over-distension should be avoided. *The injection needle should be filled (primed) with approximately 1 mL of reconstituted Botox prior to the start of injections (depending on the needle length) to remove any air.* *The needle should be inserted approximately 2 mm into the detrusor, and 20 injections of 0.5 mL each (total volume of 10 mL) should be spaced approximately 1 cm apart. For the final injection, approximately 1 mL of sterile normal saline should be injected so the full dose is delivered. After the injections are given, the saline used for bladder wall visualization should not be drained so that patients can demonstrate their ability to void prior to leaving the clinic. The patient should be observed for at least 30 minutes post-injection and until a spontaneous void has occurred.* *Clinical improvement may occur within 2 weeks. Patients should be considered for reinjection when the clinical effect of the previous injection has diminished (median duration in phase 3 clinical studies was 166 days [~24 weeks]), but no sooner than 3 months from the prior bladder injection.*	
2.	2.1 **LUCENTIS 10MG/ML SOLUTION FOR INJECTION** [Ranibizumab 10mg/ml]	➢ Indication: *The treatment of visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM).* ➢ Posology: *<u>Posology for the treatment of visual impairment due to CNV secondary to PM</u>* *Treatment is initiated with a single injection.* *If monitoring reveals signs of disease activity, e.g. reduced visual acuity and/or signs of lesion activity, further treatment is recommended.* *Monitoring for disease activity may include clinical examination, optical coherence tomography(OCT) or fluorescein angiography(FA).* *While many patients may only need one or two injections during the first year, some patients may*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

		need more frequent treatment. Therefore, monitoring is recommended monthly for the first two months and at least every three months thereafter during the first year. After the first year, the frequency of monitoring should be determined by the treating physician. *The interval between two doses should not be shorter than one month.* *There is no experience with treatment lasting for more than one year.* *Lucentis and Visudyne photodynamic therapy in CNV secondary to PM.* *There is no experience of concomitant administration of Lucentis and Visudyne.*	
3.	3.1 **Revolade Film-coated Tablet 25mg** [Eltrombopag olamine 25mg] 3.2 **Revolade Film-coated Tablet 50mg** [Eltrombopag olamine 50mg]	➢ Indication: *Revolade is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.* ➢ Posology: *Eltrombopag treatment should be initiated and remain under the supervision of a physician who is experienced in the treatment of haematological diseases or the management of chronic hepatitis C and its complications.* *<u>Posology</u>* *Eltrombopag dosing requirements must be individualised based on the patient's platelet counts. The objective of treatment with eltrombopag should not be to normalise platelet counts. In most patients, measurable elevations in platelet counts take 1-2 weeks.* *<u>Chronic hepatitis C (HCV) associated thrombocytopenia</u>* *When eltrombopag is given in combination with antivirals reference should be made to the full*	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Level 6, Quill 9, 112, Jalan Semangat No.8, Persiaran Tropicana 46300 Petaling Jaya, Selangor

		summary of product characteristics of the respective coadministered medicinal products for comprehensive details of relevant safety information or contraindications. *In clinical studies, platelet counts generally began to increase within 1 week of starting eltrombopag. The aim of treatment with eltrombopag should be to achieve the minimum level of platelet counts needed to initiate antiviral therapy, in adherence to clinical practice recommendations. During antiviral therapy, the aim of treatment should be to keep platelet counts at a level that prevents the risk of bleeding complications, normally around 50,000 – 75,000/µL. Platelet counts >75,000/µL should be avoided. The lowest dose of eltrombopag needed to achieve the targets should be used. Dose adjustments are based upon the platelet count response.* *<u>Initial dose regimen</u>* *Initiate eltrombopag at a dose of 25mg once daily. No dosage adjustment is necessary for HCV patients of East Asian ancestry or patients with mild hepatic impairment.* *<u>Monitoring and dose adjustment</u>* *The dose of eltrombopag should be adjusted in 25mg increments every 2 weeks as necessary to achieve the target platelet count required to initiate antiviral therapy. Platelet counts should be monitored every week prior to starting antiviral therapy. On initiation of antiviral therapy, the platelet count may fall, so immediate eltrombopag dose adjustments should be avoided.* *During antiviral therapy, the dose of eltrombopag should be adjusted as necessary to avoid dose reductions of peginterferon due to decreasing platelet counts that may put patients at risk of bleeding (see Table 2). Platelet counts should be monitored weekly during antiviral therapy until a stable platelet count is achieved, normally around*	

50,000 – 75,000/µL. CBCs including platelet counts and peripheral blood smears should be obtained monthly thereafter. Dose reductions on the daily dose by 25mg should be considered if platelet counts exceed the required target. Wait 2 weeks to assess the effects of this and any subsequent dose adjustments.

Do not exceed a dose of 100mg eltrombopag once daily.

Table 2: Dose adjustments of eltrombopag in HCV patients during antiviral therapy

Platelet count	*Dose adjustment or response*
< 50,000/µL following at least 2 weeks of therapy	*Increase daily dose by 25mg to a maximum of 100mg/day.*
≥ 50,000/µL to ≤ 100,000/µL	*Use lowest dose of eltrombopag as necessary to avoid dose reductions of peginterferon*
> 100,000/µL to ≤ 150,000/µL	*Decrease the daily dose by 25mg. Wait 2 weeks to assess the effects of this and any subsequent dose adjustments⬧*
> 150,000/µL	*Stop eltrombopag: increase the frequency of platelet monitoring to twice weekly. Once the platelet count is ≤ 100,000/µL, reinitiate therapy at a daily dose reduced by 25mg**

⬧ - On initiation of antiviral therapy the platelet count may fall, so immediate eltrombopag dose reductions should be avoided.
** - For patients taking 25mg eltrombopag once daily, consideration should be given to reinitiating dosing at 25mg every other day.*

<u>Discontinuation</u>
If after 2 weeks of eltrombopag therapy at 100mg

		the required platelet level to initiate antiviral therapy is not achieved, eltrombopag should be discontinued. Eltrombopag treatment should be terminated when antiviral therapy is discontinued unless otherwise justified. Excessive platelet count responses or important liver test abnormalities also necessitate discontinuation. *<u>Special populations</u>* *<u>Hepatic impairment</u>* *No dose adjustment is required for thrombocytopenia patients with chronic HCV and mild hepatic impairment (Child-Pugh score ≤ 6). Thrombocytopenic patients with chronic HCV should initiate eltrombopag at a dose of 25mg once daily (see section 5.2). After initiating the dose of eltrombopag in patients with hepatic impairment wait 2 weeks before increasing the dose. There is an increased risk for adverse events, including hepatic decompensation and thromboembolic events, in thrombocytopenic patients with advanced chronic liver disease treated with eltrombopag either in preparation for invasive procedure or in HCV patients undergoing antiviral therapy.* *<u>Older people</u>* *There are limited data on the use of eltrombopag in HCV patients aged over 75 years. Caution should be exercised in these patients.* *<u>East Asian patients</u>* *Initiate eltrombopag at a dose of 25mg once daily in HCV patients of East Asian ancestry. For ITP or HCV patients of East Asian ancestry with hepatic impairment initiate eltrombopag at a dose of 25mg once daily.* *<u>Paediatric population</u>* *Revolade is not recommended for use in children and adolescents below age 18 due to insufficient data on safety and efficacy.*	

4.	4.1 **Glivec Tablet 100mg** [Imatinib mesylate 119.5mg (equivalent to 100mg Imatinib base)] 4.2 **Glivec Tablet 400mg** [Imatinib mesylate 478mg (equivalent to 400mg Imatinib base)]	➢ Indication: *Glivec is indicated for the treatment of* • *paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy* ➢ Posology: *Dosage in Ph+ ALL* *The recommended dose of Glivec is 600mg/day for adult patients with Ph+ ALL. See section on special populations for children.* *Special populations* *<u>Children</u>* *There is no experience with the use of Glivec in children with CML below 2 years of age and with Ph+ ALL below 1 year of age. There is very limited experience in children with MDS/MPD, DFSP, GIST and HES/CEL.* *Dosing in children should be on the basis of body surface area (mg/m2). The dose of 340 mg/m2 daily is recommended for children with chronic phase and advanced phase CML and Ph+ ALL (not to exceed the total dose of 600 mg daily). Treatment can be given as a once daily dose in CML and Ph+ ALL. In CML, alternatively the daily dose may be split into two administrations – one in the morning and one in the evening.*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

<table>
<tr>
<td>5.</td>
<td>5.1 Vfend 50 mg Tablet
[Voriconazole 50 mg]

5.2 Vfend 200 mg Tablet
[Voriconazole 200 m]

5.3 Vfend IV
[Voriconazole 200 mg]

5.4 Vfend Powder for Oral Suspension 40mg/ml
[Voriconazole 40mg/ml]</td>
<td>➢ Indication:

Prophylaxis in patients ≥ 12 years old who are at high risk of developing invasive fungal infections. The indication is based on studies which includes patients ≥ 12 years old undergoing haematopoietic stem cell transplantation.

➢ Posology:

<table>
<tr><th></th><th>Intravenous</th><th colspan="2">Oral</th></tr>
<tr><th></th><th></th><th>Patients 40 kg and above</th><th>Patients less than 40 kg</th></tr>
<tr><td><u>Loading Dose Regimen (first 24 hours)</u></td><td>6 mg/kg every 12 hours (for the first 24 hours)</td><td>-</td><td>-</td></tr>
<tr><td><u>Maintenance Dose (after first 24 hours)</u>
Prophylaxis of invasive fungal infections</td><td>4 mg/kg every 12 hrs</td><td>200 mg or 5 mL every 12 hrs</td><td>100 mg or 2.5 mL every 12 hrs</td></tr>
</table>
</td>
<td>PFIZER (MALAYSIA) SDN. BHD.
Level 9-2, 10 & 11, Wisma Averis, Tower 2
Avenue 5, Bangsar South
No.8, Jalan Kerinchi
59200 Kuala Lumpur</td>
</tr>
<tr>
<td>6.</td>
<td>6.1 STIVARGA 40MG FILM-COATED TABLETS
[Regorafenib monohydrate 41.49mg (equivalent to 40mg regorafenib)]</td>
<td>➢ Indication:

Stivarga is indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.</td>
<td>BAYER CO. (MALAYSIA) SDN. BHD.
T1-14 Jaya 33, No. 3 Jalan Semangat
Seksyen 13
46200 Petaling Jaya, Selangor</td>
</tr>
</table>