Maklumat tambahan indikasi untuk upload pada laman web
Year 2013
Products Approved For Additional Indication (DCA 262 – 28 Mac 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **EVISTA TABLET 60MG** [Raloxifene hydrochloride 60mg (equivalent to raloxifene 56mg)]	➢ Indication: *Evista is indicated for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis.*	**TAKEDA MALAYSIA SDN. BHD.** Lot 3A-01, Level 3A, Block B, HP Towers, 12, Jalan Gelenggang, Bukit Damansara, 50490 Kuala Lumpur.
2.	2.1 **PROTAXOS (GRANULES FOR ORAL SUSPENSION)** [Strontium ranelate 2 gram]	➢ Indication: *Protaxos is indicated in adults.* *Treatment of osteoporosis in postmenopausal women to reduce the risk of vertebral and hip fractures.* *Treatment of osteoporosis in men at increased risk of fracture*	**SERVIER MALAYSIA SDN BHD** 1301, Level 13, Uptown 2, 47400 Damansara Utama, Selangor Darul Ehsan.
3.	3.1 **AFINITOR 2.5 MG TABLET** [Everolimus 2.5 mg] 3.2 **AFINITOR 5 MG TABLET** [Everolimus 5 mg] 3.3 **AFINITOR 10 MG TABLET** [Everolimus 10 mg]	➢ Indication: *Afinitor is indicated for the* *- treatment of adult patients with renal angiomyolipoma (AML) and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of Afinitor in the treatment of renal angiomyolipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes.*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 15, CREST, 3 Two Square, No.2, Jalan 19/1, 46300 Petaling Jaya, Selangor.

		➢ Posology: ➢ *Recommended Dose in Renal Angiomyolipoma with Tuberous Sclerosis Complex.* *The recommended dose of Afinitor is 10 mg, to be taken once daily.* ➢ *Dosing in Specials Populations* • *Pediatric Use* *Afinitor is recommended for use only in patients with SEGA who are aged >3 years.* *A prospective, open-label, single-arm trial was conducted to evaluate the safety and efficacy of Afinitor in patientswith SEGA associated with TSC. In total, 28 patients received treatment with Afinitor; median age was 11 years (range 3-34). Afinitor has not been studied in patients with SEGA < 3 years of age.* *The safety and effectiveness of Afinitor has not been established in pediatric patients with renal angiomyolipoma with TSC in the absence of SEGA.* • *Hepatic Impairment* *The safety, tolerability and pharmacokinetics of Afinitor were evaluated in a 34 subject single oral dose study of everolimus in subjects with impaired hepatic function relative to subjects with normal hepatic function. Exposure was increased in patients with mild (Child-Pugh class A), moderate (Child-Pugh class B), and severe (Child-Pugh class C) hepatic impairment.* *For advanced HR+BC, advanced PNET, advanced RCC and renal angiomyolipoma with*	

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<td>TSC patients with severe hepatic impairment, Afinitor may be used at a reduced dose if the desired benefit outweighs the risk. For patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment, a dose reduction is recommended.

For SEGA patients with severe hepatic impairment (Child-Pugh class C), Afinitor is not recommended. For SEGA patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment, adjustment to the starting dose may not be needed; however, subsequent dosing should be individualized based on therapeutic drug monitoring.</td>
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<td>4.</td>
<td>4.1 XARELTO 15MG FILM-COATED TABLET
[Rivaroxaban 15mg]

4.2 XARELTO 20MG FILM-COATED TABLET
[Rivaroxaban 20mg]</td>
<td>➢ Indication:
Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

➢ Posology:

Same as approved posology with exception to the changes in the following subheadings:

Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE
The recommended dose for the initial treatment of acute DVT or PE is 15 mg twice daily for the first three weeks followed by 20 mg once daily for the continued treatment and prevention of recurrent DVT and PE, as indicated in the table below.
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<tr><th></th><th>Dosing schedule</th><th>Maximum daily dose</th></tr>
<tr><td>Day 1 - 21</td><td>15 mg twice daily</td><td>30 mg</td></tr>
<tr><td>Day 22 and onwards</td><td>20 mg once daily</td><td>20 mg</td></tr>
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<td>BAYER CO. (M)SDN. BHD.
T1-14 Jaya 33,
No. 3 JalanSemangat,
Seksyen 13,
46200 Petaling Jaya,
Selangor.</td>
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The duration of therapy should be individualised after careful assessment of the treatment benefit against the risk for bleeding. Short duration of therapy (3 months) should be based on transient risk factors (e.g. recent surgery, trauma, immobilisation) and longer durations should be based on permanent risk factors or idiopathic DVT or PE.

If a dose is missed during the 15 mg twice daily treatment phase (day 1 - 21), the patient should take Xarelto immediately to ensure intake of 30 mg Xarelto per day. In this case two 15 mg tablets may be taken at once. The patient should continue with the regular 15 mg twice daily intake as recommended on the following day.

If a dose is missed during the once daily treatment phase (day 22 and onwards), the patient should take Xarelto immediately, and continue on the following day with the once daily intake as recommended. The dose should not be doubled within the same day to make up for a missed dose.

Special populations

Renal impairment
No dose adjustment is necessary in patients with mild renal impairment (creatinine clearance 50 - 80 ml/min).

In patients with moderate (creatinine clearance 30 - 49 ml/min) or severe (creatinine clearance 15 - 29 ml/min) renal impairment the following dosage recommendations apply:

• For the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation, the recommended dose is 15 mg once daily.

		• *For the treatment of DVT, treatment of PE and prevention of recurrent DVT and PE: Patients should be treated with 15 mg twice daily for the first 3 weeks. Thereafter, the recommended dose is 20 mg once daily. A reduction of the dose from 20mg once daily to 15mg once daily should be considered if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT and PE. The recommendation for the use of 15 mg is based on PK modelling and has not yet been studied in this clinical setting.* *Limited clinical data for patients with severe renal impairment (creatinine clearance15 - 29 ml/min)indicate that rivaroxaban plasma concentrations are significantly increased therefore, Xarelto is to be used with caution in these patients. Use is not recommended in patients with creatinine clearance < 15 ml/min.*	
5.	5.1 **HUMIRA SOLUTION FOR INJECTION** [Adalimumab 40 mg/0.8 ml]	➢ Indication: <u>*Ulcerative Colitis*</u> *Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.* ➢ Posology: *The recommended Humira induction dose regimen for adult patients with moderate to severe ulcerative colitis is 160mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days) and 80mg at week 2. After induction treatment, the recommended dose is 40mg every other week via subcutaneous injection.*	**ABBVIE SDN BHD** No. 24, Jalan Pemaju U1/15, Seksyen U1, Hicom-Glenmarie Industrial Park, 40150 Shah Alam, Selangor.

		Aminosalicylates, corticosteroids, and/or immunomodulatory agents (e.g., 6-mercaptopurine and azathioprine) may be continued during treatment with Humira. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. *Some patients who experience decrease in their response may benefit from an increase in dosing frequency to 40mg Humira every week.* *Available data suggest that clinical response is usually achieved within 2-8 weeks of treatment. Adalimumab should only be continued in patients who have responded during the first 8 weeks of therapy.*	