Maklumat tambahan indikasi untuk upload pada laman web
Year 2012
Products Approved For Additional Indication (DCA 258 – 29 November 2012)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Afinitor 10mg Tablet** [Everolimus 10 mg] 1.2 **Afinitor 5mg Tablet** [Everolimus 5 mg] 1.2 **Afinitor 2.5mg Tablet** [Everolimus 2.5 mg]	➢ Indication: *Afinitor is indicated for the* *- treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole.* ➢ Posology: *Recommended Dose in Advanced Hormonal Receptor-Positive, HER2-Negative Breast Cancer, Advanced Pancreatic Neuroendocrine Tumors and Advanced Renal Cell Carcinoma* *The recommended dose of AFINITOR is 10 mg, to be taken once daily.* *Dosing in Specials Populations* ➢ *Geriatric Use* *In the randomized advanced hormone receptor positive, HER2-negative breast cancer study, 40% of AFINITOR-treated patients were > 65 years of age, while 15% were 75 and over. No overall differences in effectiveness were observed between elderly and younger subjects. The incidence of deaths due to any cause within 28 days of the last AFINITOR dose was 6% in patients > 65 years of age compared to 2% in patients < 65 years of age. Adverse reactions leading to permanent treatment discontinuation occurred in 33% of patients > 65 years of age*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 15, Crest, 3 Two Square, No.2, Jalan 19/1, 46300 Petaling Jaya, Selangor.

		compared to 17% in patients < 65 years of age. *In the randomized advanced RCC study, 41% of AFINITOR-treated patient were > 65 years in age, while 7% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.* *No dosage adjustment is required in elderly patients.* ➢ *<u>Hepatic Impairment</u>* *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 and advanced RCC 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*	

2.	2.1 **Celebrex Capsule 100mg** [Celecoxib 100mg] 2.2 **Celebrex Capsule 200mg** [Celecoxib 200mg]	➢ Indication: *For the management of low back pain.* ➢ Posology: *Low Back Pain (LBP): Usual dosage for adults is 100mg of celecoxib orally twice daily, morning and evening after meal, or 200mg once daily.*	**PFIZER (M) SDN. BHD.** Level 9-2, 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur, Wilayah Persekutuan