Maklumat tambahan indikasi
Year 2018
Products Approved For Additional Indication (DCA 326 – 28 August 2018)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Esmya 5mg Tablets** [Ulipristal acetate 5 mg]	➢ Indication: *Ulipristal acetate is indicated for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.* ➢ Posology: *The treatment consists of one tablet of 5 mg to be taken once daily for treatment courses of up to 3 months each.* *Treatments should only be initiated when menstruation has occurred:* • *The first treatment course should start during the first week of menstruation.* • *Re-treatment courses should start at the earliest during the first week of the second menstruation following the previous treatment course completion.* *The treating physician should explain to the patient the requirement for treatment free intervals.* *Repeated intermittent treatment has been studied up to 4 intermittent courses.*	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Seksyen U8 Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor

2.	2.1 **Resolor 1mg Film Coated Tablets** [Prucalopride succinate 1.321mg per tablet] 2.2 **Resolor 2mg Film Coated Tablets** [Prucalopride succinate 2.642mg per tablet]	➢ Indication: *RESOLOR® is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya, Selangor
3.	3.1 **Zykadia 150mg Hard Capsules** [Ceritinib 150 mg]	➢ Indication: *Zykadia as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor
4.	4.1 **Afinitor 2.5mg Tablet** [Everolimus 2.5mg] 4.2 **Afinitor 5mg Tablet** [Everolimus 5mg] 4.2 **Afinitor 10mg Tablet** [Everolimus 10mg]	➢ Indication: *AFINITOR tablets are indicated for the treatment of adult patients with progressive, well-differentiated (Grade 1 or Grade 2), non-functional neuroendocrine tumours (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumours.* ➢ Posology: *Recommended Dose in Advanced Hormonal Receptor-Positive, HER2-Negative Breast Cancer, Advanced NET, Advanced RCC and Renal Angiomyolipoma with TSC.* *The recommended dose of AFINITOR is 10 mg, to be taken once daily at the same time every day. Administer either consistently with food or consistently without food (see section CLINICAL PHARMACOLOGY). AFINITOR Tablets should be*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

swallowed whole with a glass of water. Do not break or crush tablets.

Continue treatment until disease progression or unacceptable toxicity occurs.

Dose Modifications in Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer, Advanced NET, Advanced RCC and Renal Angiomyolipoma with TSC.

Adverse Reactions
Management of severe or intolerable adverse reactions may require temporary dose interruption (with or without a dose reduction of AFINITOR therapy) or discontinuation. If dose reduction is required, the suggested dose is approximately 50% lower than the daily dose previously administered (see section WARNINGS AND PRECAUTIONS).

Table 1 summarizes recommendations for dose reduction, interruption or discontinuation of AFINITOR in the management of adverse reactions. General management recommendations are also provided as applicable. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Table 1: AFINITOR Dose Adjustment and Management Recommendations for Adverse Drug Reactions

Adverse reaction	Severity[a]	AFINITOR Dose Adjustment[b] and Management Recommendations
Non-infectious pneumonitis	Grade 1 Asymptomatic, clinical or diagnostic observations only; intervention not indicated	No dose adjustment required. Initiate appropriate monitoring.

	Grade 2 Symptomatic, medical intervention indicated; limiting instrumental ADL[c]	Consider interruption of therapy, rule out infection and consider treatment with corticosteroids until symptoms improve to Grade ≤ 1. Re-initiate treatment at a lower dose. Discontinue treatment if failure to recover within 4 weeks.
	Grade 3 Severe symptoms; limiting self-care ADL[c]; O_2 indicated	Interrupt treatment until symptoms resolve to Grade ≤ 1. Rule out infection and consider treatment with corticosteroids. Consider re-initiating treatment at a lower dose. If toxicity recurs at Grade 3, consider discontinuation.
	Grade 4 Life-threatening respiratory compromise; urgent intervention indicated (e.g. tracheotomy or intubation)	Discontinue treatment, rule out infection, and consider treatment with corticosteroids.
Stomatitis	Grade 1 Asymptomatic or mild symptoms	No dose adjustment required. Manage with non-alcoholic or salt water (0.9%) mouth wash several times a day.
	Grade 2 Moderate pain; not interfering with oral intake; modified diet indicated	Temporary dose interruption until recovery to Grade ≤ 1. Re-initiate treatment at the same dose. If stomatitis recurs at Grade 2, interrupt dose until recovery to Grade ≤ 1. Re-initiate treatment at a lower dose. Manage with topical analgesic mouth treatments

		(e.g., benzocaine, butyl aminobenzoate, tetracaine hydrochloride, menthol or phenol) with or without topical corticosteroids (i.e. triamcinolone oral paste)[d].
	Grade 3 Severe pain; interfering with oral intake	Temporary dose interruption until recovery to Grade ≤ 1. Re-initiate treatment at a lower dose. Manage with topical analgesic mouth treatments (e.g., benzocaine, butyl aminobenzoate, tetracaine hydrochloride, menthol or phenol) with or without topical corticosteroids (i.e. triamcinolone oral paste)[d].
	Grade 4 Life-threatening consequences; urgent intervention indicated	Discontinue treatment and treat with appropriate medical therapy.
Other non-hematologic toxicities (excluding metabolic events)	Grade 1	If toxicity is tolerable, no dose adjustment required. Initiate appropriate medical therapy and monitor.
	Grade 2	If toxicity is tolerable, no dose adjustment required. Initiate appropriate medical therapy and monitor. If toxicity becomes intolerable, temporary dose interruption until recovery to Grade ≤ 1. Re-initiate treatment at the same dose. If toxicity recurs at Grade 2, interrupt treatment until recovery to Grade ≤ 1. Re-initiate treatment at a lower dose.
	Grade 3	Temporary dose interruption until recovery to Grade ≤ 1. Initiate appropriate medical therapy and monitor.

		Consider re-initiating treatment at a lower dose. If toxicity recurs at Grade 3, consider discontinuation.
	Grade 4	Discontinue treatment and treat with appropriate medical therapy.
Metabolic events (e.g. hyperglycemia, dyslipidemia)	Grade 1	No dose adjustment required. Initiate appropriate medical therapy and monitor.
	Grade 2	No dose adjustment required. Manage with appropriate medical therapy and monitor.
	Grade 3	Temporary dose interruption. Re-initiate treatment at a lower dose. Manage with appropriate medical therapy and monitor.
	Grade 4	Discontinue treatment and treat with appropriate medical therapy.
Thrombocyto-penia (platelet count decreased)	Grade 1 (< LLN[e] - 75,000/mm^3; < LLN[e] - 75.0 x 10^9/L)	No dose adjustment required.
	Grade 2 (< 75,000 – 50,000/mm^3; < 75.0 – 50.0 x 10^9/L)	Temporary dose interruption until recovery to Grade ≤ 1. Re-initiate treatment at a lower dose.
	Grade 3 (< 50,000 – 25,000/mm^3; < 50.0 – 25.0 x 10^9/L) OR	Temporary dose interruption until recovery to Grade ≤ 1. Re-initiate treatment at a lower dose.
	Grade 4 (< 25,000/mm^3; < 25.0 x 10^9/L)	
Neutropenia	Grade 1 (< LLN[e] -	No dose adjustment required.

(neutrophil count decreased)	1,500/mm^3; < LLN[e] - 1.5 x 10^9/L) OR	
	Grade 2 (< 1,500 - 1,000/mm^3; < 1.5 – 1.0 x 10^9/L)	
	Grade 3 (< 1,000 - 500/mm^3; < 1.0 – 0.5 x 10^9/L)	Temporary dose interruption until recovery to Grade ≤ 2. Re-initiate treatment at the same dose.
	Grade 4 (< 500/mm^3; < 0.5 x 10^9/L)	Temporary dose interruption until recovery to Grade ≤ 2. Re-initiate treatment at the same dose.
Febrile neutropenia	Grade 3 ANC[f] < 1,000/mm^3 with a single temperature of > 38.3ºC (101ºF) or a sustained temperature of ≥ 38ºC (100.4ºF) for more than one hour	Temporary dose interruption until recovery to Grade ≤ 2 and no fever. Re-initiate treatment at a lower dose.
	Grade 4 Life-threatening consequences; urgent intervention indicated	Discontinue treatment.

[a] Severity grade description: 1 = mild symptoms; 2 = moderate symptoms; 3 = severe symptoms; 4 = life-threatening symptoms. Grading based on National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE)v4.03.

[b] If dose reduction is required, the suggested dose is

			approximately 50% lower than the dose previously administered. [c] Activities of daily living (ADL). [d] Avoid using agents containing alcohol, hydrogen peroxide, iodine, and thyme derivatives in management of stomatitis as they may worsen mouth ulcers. [e]Lower limit of normal (LLN) [f]Absolute Neutrophil Count (ANC)	