Maklumat tambahan indikasi untuk upload pada laman web
Year 2013
Products Approved For Additional Indication (DCA 263 – 29 April 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **ALOXI SOLUTION FOR INJECTION 250MCG/5ML** [Palonosetron (as hydrochloride) 0.05mg/ml]	➢ Indication: *Postoperative Nausea and Vomiting* *Prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.* *As with other antiemetics, routine prophylaxis is not recommended in patients whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and vomiting must be avoided during the postoperative period, Aloxi is recommended even where the incidence of postoperative nausea and/or vomiting is low.* ➢ Posology: *Posology and method of administration* *This medicinal product should be administered by a healthcare professional under appropriate medical supervision.* *Posology* *Postoperative Nausea and Vomiting* *75 micrograms polonosetron administered as a single intravenous bolus over 10 seconds immediately before the induction of anaesthesia.*	**MUNDIPHARMA PHARMACEUTICALS SDN. BHD.** A-5-01 Level 5, Block A, PJ8, No. 23 Jalan Barat, Seksyen 8, 46050 Petaling Jaya, Selangor

2.	2.1 **ZYTIGA 250MG TABLET** [Abiraterone acetate 250mg]	➢ Indication: *The treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated* ➢ Posology: *The recommended dose is 1,000 mg (four 250mg tablets) as a single daily dose that must not be taken with food. Taking the tablets with food increases systemic exposure to abiraterone.* *ZYTIGA is to be taken with low dose prednisone or prednisolone. The recommended dose of prednisone or prednisolone is 10mg daily.* *Medical castration with LHRH analogue should be continued during treatment in patients not surgically castrated.* *Serum transaminases should be measured prior to starting treatment, every two weeks for the first three months of treatment and monthly thereafter. Blood pressure, serum potassium and fluid retention should be monitored monthly. However, patients with a significant risk for congestive heart failure should be monitored every 2 weeks for the first three months of treatment and monthly thereafter.* *In patients with pre-existing hypokalaemia or those that develop hypokalaemia whilst being treated with ZYTIGA, consider maintaining the patient's potassium level at ≥ 4.0mM.* *For patients who develop Grade ≥3 toxicities including hypertension, hypokalaemia, oedema and other non-mineralocorticoid toxicities, treatment should be withheld and appropriate medical management should be instituted. Treatment with ZYTIGA should not be reinitiated until symptoms of*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor Darul Ehsan.

		the toxicity have resolved to Grade 1 or baseline. *In the event of a missed daily dose of either ZYTIGA, prednisone or prednisolone, treatment should be resumed the following day with the usual daily dose.* *Hepatotoxicity* *For patients who develop hepatotoxicity during treatment (alanine aminotransferase [ALT] increases or aspartate aminotransferase [AST] increases above 5 times the upper limit of normal [ULN]), treatment should be withheld immediately. Re-treatment following return of liver function tests to the patient's baseline may be given at a reduced dose of 500 mg (two tablets) once daily. For patients being re-treated, serum transaminases should be monitored at a minimum of every two weeks for three months and monthly thereafter. If hepatotoxicity recurs at the reduced dose of 500 mg daily, treatment should be discontinued.* *If patients develop severe hepatotoxicity (ALT or AST 20 times the upper limit of normal) anytime while on therapy, treatment should be discontinued and patients should not be re-treated.* *Hepatic impairment* *No dose adjustment is necessary for patients with pre-existing mild hepatic impairment, Child-Pugh Class A.* *Moderate hepatic impairment (Child-Pugh Class B) has been shown to increase the systemic exposure to abiraterone by approximately four-fold following single oral doses of abiraterone acetate 1,000 mg. There are no data on the clinical safety and efficacy of multiple doses of abiraterone acetate when administered to patients with moderate or severe hepatic impairment (Child-Pugh Class B or C). No dose adjustment can be predicted. The use of ZYTIGA should be cautiously*	

		assessed in patients with moderate hepatic impairment, in whom the benefit clearly should outweigh the possible risk. ZYTIGA should not be used in patients with severe hepatic impairment. *Renal impairment* *No dose adjustment is necessary for patients with renal impairment. However, there is no clinical experience in patients with prostate cancer and severe renal impairment. Caution is advised in these patients.* *Paediatric population* *There is no relevant use of this medicinal product in the paediatric population, as prostate cancer is not present in children and adolescents.* *Method of administration* *ZYTIGA should be taken at least two hours after eating and no food should be eaten for at least one hour after taking the tablets. These should be swallowed whole with water.*	