Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 336 – 4 Julai 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **ZYTIGA 250mg tablet** [Abiraterone Acetate 250mg]	➢ Indication: *ZYTIGA is indicated in combination with prednisone or prednisolone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) who may have received up to 3 months of prior ADT.* ➢ Posology: *Dosage of prednisone or prednisolone* *For mCRPC, ZYTIGA is used with 10 mg prednisone or prednisolone daily.* *For mHSPC, ZYTIGA is used with 5 mg prednisone or prednisolone daily.*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya,Selangor
2.	2.1 **Risperdal Oral Solution** [Risperidone 1mg/ml] 2.2 **Risperdal Tablet 1mg** [Risperidone 1mg]	➢ Indication: *RISPERDAL TABLETS (1MG) AND RISPERDAL ORAL SOLUTION* *RISPERDAL is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya,Selangor

		physicians well familiar with the treatment of conduct disorder of children and adolescents. ➢ Posology: *Conduct disorder* *Children and adolescents from 5 to 18 years of age* *For subjects ≥ 50 kg, a starting dose of 0.5 mg of oral solution once daily is recommended. This dosage can be individually adjusted by increments of 0.5 mg once daily not more frequently than every other day, if needed. The oral solution is the recommended pharmaceutical form to administer 0.5 mg. The optimum dose is 1 mg once daily for most patients. Some patients, however, may benefit from 0.5 mg once daily while others may require 1.5 mg once daily. For subjects < 50 kg, a starting dose of 0.25 mg of oral solution once daily is recommended. The oral solution is the recommended pharmaceutical form to administer 0.25 mg. This dosage can be individually adjusted by increments of 0.25 mg once daily not more frequently than every other day, if needed. The optimum dose is 0.5 mg once daily for most patients. Some patients, however, may benefit from 0.25 mg once daily while others may require 0.75 mg of oral solution once daily. The oral solution is the recommended pharmaceutical form to administer 0.75 mg.* *As with all symptomatic treatments, the continued use of RISPERDAL must be evaluated and justified on an ongoing basis.* *RISPERDAL is not recommended in children less than 5 years of age, as there is no experience in children less than 5 years of age with this disorder.*	

3.	3.1 **Velcade (Bortezomib) For Injection** [Bortezomib 3.5mg]	➢ Posology: ***Posology for previously untreated multiple myeloma patients eligible for haematopoietic stem cell transplantation (induction therapy).*** *Combination therapy with dexamethasone* *VELCADE 3.5 mg powder for solution for injection is administered via intravenous or subcutaneous injection at the recommended dose of 1.3 mg/m^2 body surface area twice weekly for two weeks on days 1, 4, 8, and 11 in a 21-day treatment cycle. This 3-week period is considered a treatment cycle. At least 72 hours should elapse between consecutive doses of VELCADE.* *Dexamethasone is administered orally at 40 mg on days 1, 2, 3, 4, 8, 9, 10 and 11 of the VELCADE treatment cycle.* *Four treatment cycles of this combination therapy are administered.* *Combination therapy with dexamethasone and thalidomide* *VELCADE 3.5 mg powder for solution for injection is administered via intravenous or subcutaneous injection at the recommended dose of 1.3 mg/m^2 body surface area twice weekly for two weeks on days 1, 4, 8, and 11 in a 28-day treatment cycle. This 4-week period is considered a treatment cycle. At least 72 hours should elapse between consecutive doses of VELCADE.* *Dexamethasone is administered orally at 40 mg on days 1, 2, 3, 4, 8, 9, 10 and 11 of the VELCADE treatment cycle.* *Thalidomide is administered orally at 50 mg daily on days 1-14 and if tolerated the dose is increased to 100 mg on days 15-28 and thereafter may be further increased to 200 mg daily from cycle 2 (see Table 5). Four treatment cycles of this combination are administered. It is recommended that patients with at least partial response receive 2 additional cycles.* **Table 5:** **Posology for VELCADE combination therapy for patients with previo usly untreated multiple myeloma eligible for haematopoietic stem cell transplantation**	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya,Selangor

Vc+ Dx	**Cycles 1 to 4**				
	Week	**1**	**2**	**3**	
	Vc (1.3 mg/m^2)	Day 1, 4	Day 8, 11	Rest Period	
	Dx 40 mg	Day 1, 2, 3, 4	Day 8, 9, 10, 11	-	
Vc+ Dx+ T	**Cycle 1**				
	Week	**1**	**2**	**3**	**4**
	Vc (1.3 mg/m^2)	Day 1, 4	Day 8, 11	Rest Period	Rest Period
	T 50 mg	Daily	Daily	-	-
	T 100 mg[a]	-	-	Daily	Daily
	Dx 40 mg	Day 1, 2, 3, 4	Day 8, 9, 10, 11	-	-
	Cycles 2 to 4[b]				
	Vc (1.3 mg/m^2)	Day 1, 4	Day 8, 11	Rest Period	Rest Period
	T 200 mg[a]	Daily	Daily	Daily	Daily
	Dx 40 mg	Day 1, 2, 3, 4	Day 8, 9, 10, 11	-	-

Vc=VELCADE; Dx=dexamethasone; T=thalidomide

[a] Thalidomide dose is increased to 100 mg from week 3 of Cycle 1 only if 50 mg is tolerated and to 200mg from cycle 2 onwards if 100 mg is tolerated.

[b] Up to 6 cycles may be given to patients who achieve at least a partial response after 4 cycles.

		Dosage adjustments for transplant eligible patients *For VELCADE dosage adjustments, as described under "Dosage and Dose Modifications for Relapsed Multiple Myeloma and Relapsed Mantle Cell Lymphoma" and "Dose Modifications for Peripheral Neuropathy" should be followed.* *In addition, when VELCADE is given in combination with other chemotherapeutic medicinal products, appropriate dose reductions for these products should be considered in the event of toxicities according to the recommendations in the Summary of Product Characteristics.*	
4.	4.1 **Cubicin (Daptomycin For Injection) 500mg Vial** [Daptomycin 500mg]	➢ Indication: *Complicated Skin and Skin Structure Infections* *Pediatric (1 to 17 years of age) patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: Staphylococcus aureus (including methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis, and Enterococcus faecalis (vancomycin-susceptible isolates only).* ➢ Posology: ***Pediatric Patients (1 to 17 Years of Age)*** ***Complicated Skin and Skin Structure Infections*** *The recommended dosage regimens based on age for pediatric patients with cSSSI are shown in Table 1. CUBICIN should be administered intravenously in 0.9% sodium chloride injection once every 24 hours for up to 14 days.* ***Table 1: Recommended Dosage of CUBICIN in Pediatric Patients (1 to 17 Years of Age) with Complicated Skin and Skin StructureInfections, Based on Age***	**MERCK SHARP & DOHME (MALAYSIA) SDN BHD** Lot No. B-22-1,B-22-2, Level 22 The Ascent, Paradigm No. 1 Jalan SS 7/26A, Kelana Jaya 47301 Petaling Jaya, Selangor

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<tr><th>Age group</th><th>Dosage*</th><th>Duration of therapy</th></tr>
<tr><td>12 to 17 years</td><td>5 mg/kg once every 24 hours infused over 30 minutes</td><td rowspan="4">Up to 14 days</td></tr>
<tr><td>7 to 11 years</td><td>7 mg/kg once every 24 hours infused over 30 minutes</td></tr>
<tr><td>2 to 6 years</td><td>9 mg/kg once every 24 hours infused over 60 minutes</td></tr>
<tr><td>1 to < 2 years</td><td>10 mg/kg once every 24 hours infused over 60 minutes</td></tr>
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*Recommended dosage is for pediatric patients (1 to 17 years of age) with normal renal function. Dosage adjustment for pediatric patients with renal impairment has not been established
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<td>5.</td>
<td>5.1 Dexilant Delayed Release Capsules 30mg
[Dexlansopra-zole 30mg]

5.2 Dexilant Delayed Release Capsules 60mg
[Dexlansopra-zole 60mg]</td>
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➢ Indication:

<u>Symptomatic Non-Erosive Gastroesophageal Reflux Disease</u>
DEXILANT is indicated in patients 12 years of age and older for the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for 4 weeks.

➢ Posology:

DEXILANT is available as capsules in 30 mg and 60 mg strengths for adult use and patients 12 years of age and older. Directions for use in each indication are summarized in Table 10.

<table>
<tr><th colspan="3">Table 10: DEXILANT Dosing Recommendations</th></tr>
<tr><th>Indication (Adult)</th><th>Recommended Dose</th><th>Frequency</th></tr>
<tr><td>Healing of EE</td><td>60 mg</td><td>Once daily for up to 8 weeks</td></tr>
<tr><td>Maintenance of Healed EE and relief of heartburn</td><td>30 mg</td><td>Once daily*</td></tr>
<tr><th>Indication (12 years and older)</th><th>Recommended Dose</th><th>Frequency</th></tr>
<tr><td>Symptomatic Non-Erosive GERD</td><td>30 mg</td><td>Once daily for 4 weeks</td></tr>
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<td>TAKEDA MALAYSIA SDN. BHD.
Unit TB-L13-1, Level 13, Tower B,
Plaza 33, No.1, Jalan Kemajuan, Seksyen 13
46200 Petaling Jaya,
Selangor</td>
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		*Controlled studies did not extend beyond 6 months in adults. *Pediatric Use* *Safety and effectiveness of DEXILANT in pediatric patients (less than 12 years of age) have not been established*.	