Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 332 – 7 Mac 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Adcetris 50mg, powder for concentrate for solution for infusion** [Brentuximab Vedotin 50mg]	➢ Indication: *Adcetris is indicated for the treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy.* ➢ Posology: *The recommended dose is 1.8 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks.* *Do not administer as an IV push or bolus.* *The recommended starting dose in patients with severe renal impairment is 1.2 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks. Patients with renal impairment should be closely monitored for adverse events.* *The recommended starting dose in patients with hepatic impairment is 1.2 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks. Patients with hepatic impairment should be closely monitored for adverse events.* *For patients with HL at risk of relapse or progression following ASCT, Adcetris treatment should start following recovery from ASCT based on medical judgment. These patients should receive up to 16 cycles.* *If patient's weight is more than 100 kg, the dose calculation should use 100 kg. Continue treatment until disease progression or unacceptable toxicity. Patients who achieve stable disease or better should receive a minimum of 8 cycles. There is a clinical experience with*	**TAKEDA MALAYSIA SDN BHD.** Unit TB-L 13-1, Level 13 Tower B, Plaza 33 No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

		treating patients through 16 cycles (approximately 1 year). Complete blood counts should be monitored prior to administration of each dose of this treatment. Patients should be monitored during and after infusion. <u>Patients with cutaneous T-Cell Lymphoma (CTCL) should receive up to 16 cycles</u>.	
2.	2.1 **Repatha Solution for Injection in Pre-filled Syringe 140 mg/ml (evolocumab)** [Evolocumab 140 mg/ml] 2.2 **Repatha Solution for Injection in Pre-filled Autoinjector 140 mg/ml (evolocumab)** [Evolocumab 140 mg/ml]	➢ Indication: <u>*Prevention of cardiovascular events*</u> *Repatha is indicated as an adjunct to diet and standard of care therapy (including moderate- to high-intensity statin therapy alone or in combination with other lipid-lowering therapy), to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adult patients with atherosclerotic cardiovascular disease.* <u>*Primary hyperlipidemia (including heterozygous familial hypercholesterolemia)*</u> *Repatha is indicated for the reduction of elevated low-density lipoprotein cholesterol (LDL-C) in adult patients with primary hyperlipidemia (including heterozygous familial hypercholesterolemia):* • *As an adjunct to diet and statin therapy, with or without other lipid-lowering therapies, in patients who require additional lowering of LDL-C* • *As an adjunct to diet, alone or in combination with non-statin lipid-lowering therapies, in patients for whom a statin is contraindicated.* <u>*Homozygous familial hypercholesterolemia*</u> *Repatha is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.*	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8 Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor

<table>
<tr>
<td>3.</td>
<td>3.1 Symbicort turbuhaler 160/4.5 mcg/dose
[Budesonide 160mcg/Formoterol fumarate dihydrate 4.5mcg]

3.2 Symbicort turbuhaler 320/9 mcg/dose
[Budesonide 320mcg/Formoterol fumarate dihydrate 9mcg]</td>
<td>➢ Indication:

<u>Chronic Obstructive Pulmonary Disease (COPD)</u>
Symbicort Turbuhaler is indicated in adults, aged 18 years and older, for the symptomatic treatment of patients with COPD with FEV1 < 70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.</td>
<td>ASTRAZENECA SDN. BHD.
Level 11 & 12, Nucleus Tower
No. 10, Jalan PJU 7/6
Mutiara Damansara
47800 Petaling Jaya, Selangor</td>
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<td>4.</td>
<td>4.1 CUBICIN (DAPTOMYCIN FOR INJECTION) 500MG VIAL
[Daptomycin 500mg]</td>
<td>➢ Indication:

Pediatric patients (1 to 17 years of age) with S. aureus bloodstream infections (bacteremia) caused by methicillin-susceptible and methicillin-resistant isolates.

➢ Posology:

The recommended dosage regimens based on age for pediatric patients with S. aureus bloodstream infections (bacteremia) are shown in Table 6. CUBICIN should be administered intravenously in 0.9% sodium chloride injection once every 24 hours for up to 42 days.

Table 6: Recommended Dosage of CUBICIN in Pediatric Patients (1 to 17 Years of Age) with S. aureus Bloodstream Infections, Based on Age

<table>
<tr><th>Age group</th><th>Dosage*</th><th>Duration of therapy(1)</th></tr>
<tr><td>12 to 17 years</td><td>7 mg/kg once every 24 hours infused over 30 minutes</td><td rowspan="2">Up to 42 days</td></tr>
<tr><td>7 to 11 years</td><td>9 mg/kg once every 24 hours infused over 30 minutes</td></tr>
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</td>
<td>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</td>
</tr>
</table>

1 to 6 years	*12 mg/kg once every 24 hours infused over 60 minutes*	

**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.*

1) *Minimum duration for pediatric bacteremia should be in accordance with the perceived risk of complications in the individual patient*

The dosage regimen for CUBICIN pediatric patients with renal impairment has not been established.

Preparation of CUBICIN for Administration

<u>Pediatric Patients (1 to 17 Years of Age)</u>

Intravenous Infusion over a period of 30 or 60 minutes

- *For IV infusion over a period of 30 minutes in pediatric patients, reconstituted CUBICIN (concentration of 50 mg/ml) is further diluted, using aseptic technique, into a 50 mL IV infusion bag containing 0.9% sodium chloride injection. The infusion rate should be maintained at 1.67 mL/min over the 30 minute period.*

- *For IV infusion over a period of 60 minutes in pediatric patients, reconstituted CUBICIN (concentration of 50 mg/ml) is further diluted, using aseptic technique, into an IV infusion bag containing 25 mL of 0.9% sodium chloride injection. The infusion rate should be maintained at 0.42 mL/min over the 60 minute period.*

5.	5.1 **Glucophage XR 500mg Tablet** [Metformin hydrochloride 500mg] 5.2 **Glucophage XR 750mg Tablet** [Metformin hydrochloride 750mg] 5.3 **Glucophage XR 1000mg Extended Release Tablet** [Metformin hydrochloride 1000mg]]	➢ Indication: *Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG*, and/or increased HbA1C who are:* - *at high risk for developing overt type 2 diabetes mellitus (see section Pharmacodynamic properties) and* - *still progressing towards type 2 diabetes mellitus despite implementation of intensive lifestyle change for 3 to 6 months* *Treatment with Glucophage XR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section Pharmacodynamic properties).* *Lifestyle modifications should be continued when metformin is initiated, unless the patient is unable to do so because of medical reasons.* **IGT: Impaired Glucose Tolerance; IFG: Impaired Fasting Glucose* ➢ Posology: ***PRODUCT NAME*** / ***POSOLOGY*** *Glucophage XR 500mg Tablet* / *Reduction in the risk or delay of the onset of type 2 diabetes* • *Metformin should only be considered where intensive lifestyle modifications for 3 to 6 months have not resulted in adequate glycaemic control.* • *The therapy should be initiated with one tablet Glucophage XR 500 mg once daily with the evening meal.* • *After 10 to 15 days dose adjustment on the basis of blood glucose measurements*	**MERCK SDN. BHD.** Level 3, Menara Sunway Annexe Jalan Lagoon Timur, Bandar Sunway 46150 Petaling Jaya, Selangor

	is recommended (OGTT and/or FPG and/or HbA1C values to be within the normal range). A slow increase of dose may improve gastro-intestinal tolerability. The maximum recommended dose is 4 tablets (2000mg) once daily with the evening meal. • *It is recommended to regularly monitor (every 3-6 months) the glycaemic status (OGTT and/or FPG and/or HbA1C value) as well as the risk factors to evaluate whether treatment needs to be continued, modified or discontinued.* • *A decision to re-evaluate therapy is also required if the patient subsequently implements improvements to diet and/or exercise, or if changes to the medical condition will allow increased lifestyle interventions to be possible.* *Elderly:* *Benefit in the reduction of risk or delay of the onset of type 2 diabetes mellitus has not been established in patients 75 years and older (see section Pharmacodynamic properties) and metformin initiation is therefore not recommended in these patients (see section Special warnings and special precautions for use).*
Glucophage XR 750 mg Tablet	*Reduction in the risk or delay of the onset of type 2 diabetes* • *Metformin should only be considered where intensive lifestyle modifications for 3 to 6 months have not resulted in adequate glycaemic control.* • *The therapy should be*

				initiated with one tablet Glucophage XR 500 mg once daily with the evening meal. • *After 10 to 15 days dose adjustment on the basis of blood glucose measurements is recommended (OGTT and/or FPG and/or HbA1C values to be within the normal range). A slow increase of dose may improve gastro-intestinal tolerability. The maximum recommended dose of Glucophage XR 750 mg is 2 tablets (1500mg) once daily with the evening meal.* • *It is recommended to regularly monitor (every 3-6 months) the glycaemic status (OGTT and/or FPG and/or HbA1C value) as well as the risk factors to evaluate whether treatment needs to be continued, modified or discontinued.* • *A decision to re-evaluate therapy is also required if the patient subsequently implements improvements to diet and/or exercise, or if changes to the medical condition will allow increased lifestyle interventions to be possible.* *Elderly:* *Benefit in the reduction of risk or delay of the onset of type 2 diabetes mellitus has not been established in patients 75 years and older (see section Pharmacodynamic properties) and metformin initiation is therefore not recommended in these patients (see section Special warnings and precautions for use).*	

			Glucophage XR 1000mg Extended Release Tablet	*Reduction in the risk or delay of the onset of type 2 diabetes* • *Metformin should only be considered where intensive lifestyle modifications for 3 to 6 months have not resulted in adequate glycaemic control.* • *The therapy should be initiated with one tablet Glucophage XR 500 mg once daily with the evening meal.* • *After 10 to 15 days dose adjustment on the basis of blood glucose measurements is recommended (OGTT and/or FPG and/or HbA1C values to be within the normal range). A slow increase of dose may improve gastro-intestinal tolerability. The maximum recommended dose of Glucophage XR 1000 mg is 2 tablets (2000 mg) once daily with the evening meal.* • *It is recommended to regularly monitor (every 3-6 months) the glycaemic status (OGTT and/or FPG and/or HbA1C value) as well as the risk factors to evaluate whether treatment needs to be continued, modified or discontinued.* • *A decision to re-evaluate therapy is also required if the patient subsequently implements improvements to diet and/or exercise, or if changes to the medical condition will allow increased lifestyle interventions to be possible.* *Elderly:* *Benefit in the reduction of risk or delay of the onset of type 2 diabetes mellitus has not been established in*	

				patients 75 years and older (see section Pharmacodynamic properties) and metformin initiation is therefore not recommended in these patients (see section Special warnings and precautions for use).	