Maklumat tambahan indikasi untuk upload pada laman web
Year 2014
Products Approved For Additional Indication (DCA 283 – 23 Disember 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	**ADACEL SUSPENSION FOR INJECTION** [Each single dose (0.5ml) contains: i. Tetanus Toxoid 5LfU ii. Diphtheria Toxoid 2LfU Acellular Pertussis: iii. Pertussis Toxoid (PT) 2.5µg iv. Pertussis Filamentous Haemagglutinin(FHA) 5µg v. Pertussis Pertactin (PRN) 3 µg vi. Pertussis Fimbriae Types 2 and 3 (FIM) 5 µg]	➢ Indication: *Adacel is indicated for active booster immunization for the prevention of tetanus, diphtheria and pertussis (whooping cough) in persons 4 years of age and older.* *In accordance with local recommendations, Adacel may be considered as an alternative for the fifth dose of tetanus, diphtheria and acellular pertussis vaccine (DTaP) in children 4 through 6 years of age, concomitantly administered with Inactivated Poliomyelitis Vaccine (IPV) at separate sites to complete the vaccination series for this age, when indicated.* *Persons who have had tetanus, diphtheria or pertussis should still be immunized since these clinical infections do not always confer immunity. Human Immunodeficiency Virus(HIV)-infected persons, both asymptomatic and symptomatic, should be immunized against tetanus, diphtheria and pertussis according to standard schedules.* *Adacel is not to be used for the treatment of disease caused by Bordetellapertussis, Corynebacterium diphtheriae or Clostridium tetani infections.* *Pediatrics* *Adacel is not indicated for immunization of children below the age of 4 years.* *Tetanus Prophylaxis in Wound Management* *The need for active immunization with a tetanus toxoid-containing preparation such as Td Adsorbed vaccine or Adacel, with or without passive immunization with Tetanus Immune Globulin, depends on both the condition of the wound and the patient's vaccination history.*	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18,Tower B, Plaza 33 No.1, Jalan Kemajuan, Seksyen 13 46100 Petaling Jaya, Selangor

- Posology:

The immunization schedule with Adacel should follow local recommendations. Adacel (0.5ml) should be administered as a booster dose by the intramuscular route.
Re-dosing with Adacel can be used to boost immunity to diphtheria, tetanus and pertussis at 5- to 10-year intervals in adolescents and adults.
The preferred site is into the deltoid muscle.
Fractional doses (doses<0.5ml) should not be given. The effect of fractional doses on the safety and efficacy has not been determined.
The use of ADACEL in management of tetanus-prone wounds should follow local recommendations.

History of tetanus vaccination	Time since last dose	Type of wound	Tdap, DTap combinations, DT, Tdap (as appropriate)	Tetanus immunoglobulin* (TIG)
≥ 3 doses	<5 yrs	Clean minor wounds All other wounds †	No No	No No#
≥ 3 doses	5-10 yrs	Clean minor wounds All other wounds †	No Yes	No No#
≥ 3 doses	>10 yrs	Clean minor wounds All other wounds †	Yes Yes	No No#
< 3 doses or uncertain§		Clean minor wounds All other wounds †	Yes Yes	No Yes

		* *The recommended dose for TIG is 250 IU, given by IM injection, as soon as practicable after the injury. If more than 24 hours have elapsed, 500 IU should be given. Because of its viscosity, TIG should be given to adults using a 21 gauge needle. For children, it can be given slowly using a 23 gauge needle.* † *All wounds other than clean minor wounds should be considered "tetanus-prone"* # *Individuals with humoral immune deficiency (including HIV infected persons who have immunodeficiency) should be given TIG if they have received a tetanus-prone injury, regardless of the time since their last dose of tetanus-containing vaccine.* § *Persons who have no documented history of a primary vaccination course (3 doses) with a tetanus toxoid-containing vaccine should receive all missing doses and must receive TIG.*	
2.	**FOSTER 100/6 MCG/DOSE PRESSURISED INHALATION SOLUTION** [Beclometasone dipropionate 100mcg and formoterol fumarate dihydrate 6mcg]	➢ Indication: <u>*COPD*</u> *Symptomatic treatment of patients with severe COPD (FEV1<50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.* ➢ Posology: <u>COPD</u> Dose recommendations for adults 18 years and above: Two inhalations twice daily.	**ORIENT EUROPHARMA (M) SDN BHD** 33,Jalan U1/30, Seksyen U1 40150 Shah Alam, Selangor

3.	**DACOGEN (DECITABINE) FOR INJECTION 50MG/VIAL** [Decitabine 50mg/vial]	➢ Indication: *For the treatment of adult patients aged 65 and above with newly diagnosed de novo or secondary acute myeloid leukemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.* ➢ Posology: *<u>Treatment Regimen in Acute Myeloid Leukemia</u>* *In a treatment cycle, DACOGEN is administered at a dose of 20mg/m^2 body surface area by intravenous infusion over 1 hour repeated daily for 5 consecutive days (i.e., a total of 5 doses per treatment cycle). The total daily dose must not exceed 20mg/m^2 and the total dose per treatment cycle must not exceed 100mg/m^2. If a dose is missed, treatment should be resumed as soon as possible. The cycle should be repeated every 4 weeks depending on the patient's clinical response and observed toxicity. It is recommended that patients be treated for a minimum of 4 cycles; however, a complete or partial remission may take longer than 4 cycles to be obtained. Treatment may be continued as long as the patient shows response, continues to benefit or exhibits stable disease, i.e., in the absence of overt progression.* *If after 4 cycles, the patient's haematological values (e.g., platelet counts or absolute neutrophil count), have not returned to pre-treatment levels or if disease progression occurs (peripheral blast counts are increasing or bone marrow blast counts are worsening), the patient may be considered to be a nonresponder and alternative therapeutic options to Dacogen should be considered.* *Pre-medication for the prevention of nausea and vomiting is not routinely recommended but may be administered if required.* *In AML*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya, Selangor

		Myelosuppression and adverse events related to myelosuppression (thrombocytopenia, anaemia, neutropenia, and febrile neutropenia) are common in both treated and untreated patients with AML. Complications of myelosuppression include infections and bleeding. Treatment may be delayed at the discretion of the treating physician, if the patient experiences myelosuppression-associated complications, such as those described below: • *Febrile neutropenia (temperature ≥ 38.5ºC and absolute neutrophil count < 1,000/µL)* • *Active viral, bacterial or fungal infection (i.e., requiring intravenous anti-infectives or extensive supportive care)* • *Hemorrhage (gastrointestinal, genito-urinary, pulmonary with platelets < 25,000/µL or any central nervous system hemorrhage)* *Treatment with DACOGEN may be resumed once these conditions have improved or have been stabilized with adequate treatment (anti-infective therapy, transfusions, or growth factors).* *In clinical studies, approximately one-third of patients receiving Dacogen required a dose-delay. Dose reduction is not recommended.*	
4.	**PRADAXA 150MG, HARD CAPSULES** [Dabigatran etexilate]	➢ Indication: *150mg capsule:* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.* ➢ Posology: <u>*Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):*</u> *The recommended daily dose of Pradaxa is 300 mg taken as one 150 mg capsule twice daily following treatment with a parenteral anticoagulant for at least*	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15 Wisma UOA Damansara II No 6, Jalan Changkat Semantan Damansara Heights 50490 Kuala Lumpur

		5 days. The duration of therapy should be individualised after careful assessment of the treatment benefit against the risk for bleeding (see "Special warnings and precautions"). Short duration of therapy (at least 3 months) should be based on transient risk factors (e.g. recent surgery, trauma, immobilisation) and longer durations should be based on permanent risk factors or idiopathic DVT or PE. *<u>Reduction of the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation:</u>* *<u>Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):</u>* *For the following groups the recommended daily dose of Pradaxa is 220 mg taken as one 110 mg capsule twice daily:* • *Patients aged 80 years or above* • *Patients who receive concomitant verapamil* *For the following groups the daily dose of Pradaxa of 300 mg or 220 mg should be selected based on an individual assessment of the thromboembolic risk and the risk of bleeding:* • *Patients between 75-80 years* • *Patients with moderate renal impairment* • *Patients with gastritis, esophagitis or gastroesophageal reflux* • *Other patients at increased risk of bleeding* *For DVT/PE the recommendation for the use of Pradaxa 220 mg taken as one 110 mg capsule twice daily is based on pharmacokinetic and pharmacodynamic analyses and has not been studied in this clinical setting.* *In case of intolerability to dabigatran, patients should be instructed to immediately consult their treating physician in order to be switched to alternate acceptable treatment options for prevention of stroke and SEE associated with atrial fibrillation or for DVT/PE.*	

		<u>Special patient populations:</u> *<u>Renal impairment:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *Treatment with Pradaxa in patients with severe renal impairment (CrCL < 30 mL/min) is contraindicated.* *No dose adjustment is necessary in patients with mild renal impairment (CrCL 50 - ≤ 80 mL/min). For patients with moderate renal impairment (CrCL 30-50 mL/min) the recommended dose of Pradaxa is also 300 mg taken as one 150 mg capsule twice daily. However, for patients with high risk of bleeding, a dose reduction of Pradaxa to 220 mg taken as one 110 mg capsule twice daily should be considered. Close clinical surveillance is recommended in patients with renal impairment.* *<u>Elderly:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *Patients between 75-80 years should be treated with a daily dose of 300 mg taken as one 150 mg capsule twice daily. A dose of 220 mg taken as one 110 mg capsule twice daily can be individually considered, at the discretion of the physician, when the thromboembolic risk is low and the bleeding risk is high.* *Patients aged 80 years or above should be treated with a daily dose of 220 mg taken as one 110 mg capsule twice daily due to the increased risk of bleeding in this population.* *As renal impairment may be frequent in the elderly (>75 years), renal function should be assessed by calculating the CrCL prior to initiation of treatment with Pradaxa to exclude patients with severe renal impairment (i.e. CrCL < 30 mL/min). The renal function should also be assessed at least once a year in patients treated with Pradaxa or more*	

		frequently as needed in certain clinical situations when it is suspected that the renal function could decline or deteriorate (such as hypovolemia, dehydration, and with certain comedications, etc). *<u>Gender</u>* *Given the available clinical and kinetic data, no dose adjustment is necessary.* *<u>Concomitant use of Pradaxa with strong P-glycoprotein inhibitors, i.e. amiodarone, quinidine or verapamil:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *No dose adjustment is necessary for concomitant use of amiodarone or quinidine.* *Dosing should be reduced to 220 mg taken as one 110 mg capsule twice daily in patients who receive concomitantly dabigatran etexilate and verapamil. In this situation, Pradaxa and verapamil should be taken at the same time.* *<u>Patients at risk of bleeding:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *Patients with an increased bleeding risk should be closely monitored clinically (looking for signs of bleeding or anaemia). Dose adjustment should be decided at the discretion of the physician, following assessment of the potential benefit and risk to an individual patient. A coagulation test (see section 4.4) may help to identify patients with an increased bleeding risk caused by excessive dabigatran exposure. When excessive dabigatran exposure is identified in patients at high risk of bleeding, a dose of 220 mg taken as one 110 mg capsule twice daily is recommended. When clinically relevant bleeding occurs, treatment should be interrupted.* *For subjects with gastritis, esophagitis, or gastroesophageal reflux, the dose of 220 mg taken*	

		as one 110 mg capsule twice daily may be considered due to the elevated risk of major gastro-intestinal bleeding. *<u>Hepatic impairment</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *Patients with elevated liver enzymes >2 upper limit of normal (ULN) were excluded inthe main trials. No treatment experience is available for this subpopulation of patients, and therefore the use of Pradaxa is not recommended in this population. Hepatic impairment or liver disease expected to have any impact on survival is contraindicated.* *<u>Children and adolescents:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *The safety and efficacy of Pradaxa in children from birth to less than 18 years of age have not yet been established. No recommendation on a posology can be made.* *<u>Switching from PRADAXA treatment to parenteral anticoagulant:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *Wait 12 hours after the last dose before switching from PRADAXA to a parenteral anticoagulant.* *<u>Switching from Vit. K antagonists to PRADAXA:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *The Vit. K antagonist should be stopped. PRADAXA can be given as soon as the INR is < 2.0.* *<u>Switching from PRADAXA® to Vit. K antagonists (VKA):</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of*	

		recurrent DVT, and PE in adults (DVT/PE): *The starting time of the VKA should be adjusted according to the patient´s CrCL as follows:* *• CrCL ≥ 50 ml/min, start VKA 3 days before discontinuing dabigatran etexilate.* *• CrCL ≥ 30-< 50 ml/min, start VKA 2 days before discontinuing dabigatran etexilate.* *Because Pradaxa can increase INR, the INR will better reflect VKA's effect only after Pradaxa has been stopped for at least 2 days. Until then, INR values should be interpreted with caution.* *<u>Cardioversion:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *Patients can stay on PRADAXA while being cardioverted.* *<u>Missed dose:</u>* *Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT, and PE in adults (DVT/PE):* *A forgotten PRADAXA dose may still be taken up to 6 hours prior to the next scheduled dose. From 6 hours prior to the next scheduled dose on, the missed dose should be omitted.* *Do not take a double dose to make up for missed individual doses.* *<u>Method of administration</u>* *Pradaxa can be taken with or without food. Pradaxa should be swallowed whole with a glass of water, to facilitate delivery to the stomach.* *Patients should be instructed not to open the capsule as this may increase the risk of bleeding.*	

5.	**DIPHERELINE P.R. 11.25MG POWDER FOR SUSPENSION FOR INTRAMUSCULAR INJECTION** [Triptorelin pamoate]	➢ Indication: *Treatment of locally advanced prostate cancer when used alone or as concomitant and adjuvant to radiotherapy.* *Treatment of metastatic prostate cancer.*	**A. MENARINI SINGAPORE PTE. LTD.** Level 2, No. 10 Jalan Bersatu 13/4 46200 Petaling Jaya, Selangor
6.	**DIPHERELINE P.R. 3.75MG** [Triptorelin pamoate]	➢ Indication: *Treatment of locally advanced prostate cancer when used alone or as concomitant and adjuvant to radiotherapy.* *Treatment of metastatic prostate cancer.*	**A. MENARINI SINGAPORE PTE. LTD.** Level 2, No. 10 Jalan Bersatu 13/4 46200 Petaling Jaya, Selangor
7.	**DIPHERELINE P.R. 3.75MG** [Triptorelin pamoate]	➢ Indication: *Precocious puberty (before 8 years in girls and 10 years in boys).* ➢ Posology: *The treatment of children with triptorelin should be under the overall supervision of the paediatric endocrinologist or of a paediatrician or endocrinologist with expertise in the treatment of central precocious puberty.* • *Children under 20kg in body weight: half (1/2) a dose by intramuscular route, every 4 weeks (28 days), i.e. administer half the volume of the reconstituted suspension.* • *Children between 20 and 30kg in body weight: two-thirds (2/3) of the dose by intramuscular route, every 4 weeks (28 days), i.e. administer two-thirds of the volume of the reconstituted suspension.* • *Children over 30kg in body weight: one intramuscular injection every 4 weeks (28 days), i.e. administer the full volume of reconstituted suspension.* *Treatment should be stopped around the physiological age of puberty in boys and girls and*	**A. MENARINI SINGAPORE PTE. LTD.** Level 2, No. 10 Jalan Bersatu 13/4 46200 Petaling Jaya, Selangor

		should not be continued in girls with a bone maturation of more than 12 years. There are limited data available in boys relating to the optimum time to stop treatment based on the bone age, however it is advised that treatment is stopped in boys with a bone maturation age of 12-14 years.	