Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 397, 10 Jun 2024

Products approved for additional indication (DCA 397 – 10 Jun 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	PLAVIX TABLET 75MG [Clopidogrel Hydrogen Sulphate 97.875mg (equivalent to 75mg clopidogrel)] Plavix Tablet 300mg [Clopidogrel Hydrogen Sulphate 391.5mg (equivalent to 300mg clopidogrel)]	**INDICATION :** Adult patients suffering from acute coronary syndrome:- • ST segment elevation acute myocardial infarction, in combination with ASA in patients undergoing percutaneous coronary intervention (including patients undergoing a stent placement) or medically treated patients eligible for thrombolytic/fibrinolytic therapy. **POSOLOGY :** • Adults and elderly Clopidogrel should be given as a single daily dose of 75 mg. In patients suffering from acute coronary syndrome: - ST segment elevation acute myocardial infarction: For medically treated patients eligible for thrombolytic/fibrinolytic therapy, clopidogrel should be given as a single daily dose of 75 mg initiated with a 300-mg loading dose in combination with ASA and with or without thrombolytics. For medically treated patients over 75 years of age clopidogrel should be initiated without a loading dose. Combined therapy should be started as early as possible after symptoms start and continued for at least four weeks. The benefit of the combination of clopidogrel with ASA beyond four weeks has not been studied in this setting.	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

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		- When percutaneous coronary intervention (PCI) is intended: o Clopidogrel should be initiated at a loading dose of 600 mg in patients undergoing primary PCI and in patients undergoing PCI more than 24 hours of receiving fibrinolytic therapy. In patients ≥ 75 years old the 600 mg LD should be administered with caution. o Clopidogrel 300 mg loading dose should be given in patients undergoing PCI within 24 hours of receiving fibrinolytic therapy. Clopidogrel treatment should be continued at 75 mg once a day with ASA 75 mg – 100 mg daily. Combined therapy should be started as early as possible after symptoms start and continued up to 12 months.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Pamorelin Powder for Suspension for Injection 3.75 mg [Triptorelin embonate 3.75mg]	**INDICATION:** Pamorelin 3.75 mg is indicated for the treatment of endometriosis. See section 5.1. **POSOLOGY:** <u>Endometriosis:</u> In women the treatment of endometriosis with Pamorelin 3.75 mg begins during the early follicular phase and should not exceed 6 months.	**ORIENT EUROPHARMA (M) SDN. BHD.** E-08, Garden Shoppe, One City, Jalan USJ 25/1C, 47650 Subang Jaya, Selangor.