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Year 2014
Products Approved For Additional Indication (DCA 273 – 27 February 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **ILARIS 150MG POWDER FOR SOLUTION FOR INJECTION** [Canakinumab 150mg/ml]	➢ Indication: *Ilaris is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children aged 2 years and older including:* • *Familial Cold Auto inflammatory Syndrome (FCAS) /Familial Cold Urticaria (FCU),* • *Muckle-Wells Syndrome (MWS),* • *Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA).* ➢ Posology: *Treatment should be initiated and supervised by a specialist physician experienced in the diagnosis and treatment of the relevant indication.* *After proper training in the correct injection technique, patients or their caregivers may inject Ilaris if the physician determines that it is appropriate and with medical follow-up as necessary (see section on Instructions For Use and Handling).* *Dosage for CAPS* *The recommended starting dose of Ilaris for CAPS patients is:* *Adults and children ≥ 4 years of age:* – *150 mg for patients with body weight > 40 kg* – *2 mg/kg for patients with body weight ≥ 15 kg and ≤ 40 kg* – *4 mg/kg for patients with body weight ≥ 7.5 kg and < 15 kg* *Children 2 to < 4 years of age:* – *4 mg/kg for patients with body weight ≥ 7.5 kg*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

		This is administered every eight weeks as a single dose via subcutaneous injection. *For patients with a starting dose of 150 mg or 2 mg/kg, if a satisfactory clinical response (resolution of rash and other generalised inflammatory symptoms) has not been achieved 7 days after treatment start, a second dose of Ilaris at 150 mg or 2 mg/kg can be considered. If a full treatment response is subsequently achieved, the intensified dosing regimen of 300 mg or 4 mg/kg every 8 weeks should be maintained. If a satisfactory clinical response has not been achieved 7 days after this increased dose, a third dose of Ilaris at 300 mg or 4 mg/kg can be considered. If a full treatment response is subsequently achieved, the intensified dosing regimen of 600 mg or 8 mg/kg every 8 weeks should be maintained.* *For patients with a starting dose of 4 mg/kg, if a satisfactory clinical response has not been achieved 7 days after treatment start, a second dose of Ilaris 4 mg/kg can be considered. If a full treatment response is subsequently achieved, maintaining the intensified dosing regimen of 8 mg/kg every 8 weeks should be maintained.* *Clinical experience with dosing at intervals of less than 4 weeks or at doses above 600 mg or 8 mg/kg is limited.*	
2.	2.1 **PROLIA SOLUTION FOR INJECTION 60MG** [Denosumab 60mg/ml] 2.2 **PROLIA SOLUTION FOR INJECTION 60MG PRE-FILLED SYRINGE** [Denosumab 60mg/ml]	➢ Indication: • *Male Osteoporosis* *PROLIA is indicated as a treatment to increase bone mass in men with osteoporosis at increased risk of fracture.*	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Level 6, Quill 9, 112, Jalan Semangat No.8, Persiaran Tropicana 46300 Petaling Jaya, Selangor

3.	3.1 **Caduet Film-Coated Tablet 5mg/10mg** [Amlodipine besylate 5mg & Atorvastatin calcium 10mg] 3.2 **Caduet Film-Coated Tablet 5mg/20mg** [Amlodipine besylate 5mg & Atorvastatin calcium 20mg] 3.3 **Caduet Film-Coated Tablet 5mg/40mg** [Amlodipine besylate 5mg & Atorvastatin calcium 40mg] 3.4 **Caduet Film-Coated Tablet 5mg/80mg** [Amlodipine besylate 5mg & Atorvastatin calcium 80mg] 3.5 **Caduet Film-Coated Tablet 10mg/10mg** [Amlodipine besylate 10mg & Atorvastatin calcium 10mg] 3.6 **Caduet Film-Coated Tablet 10mg/20mg** [Amlodipine besylate 10mg & Atorvastatin calcium 20mg] 3.7 **Caduet Film-Coated Tablet 10mg/40mg** [Amlodipine besylate 10mg & Atorvastatin calcium 40mg] 3.8 **Caduet Film-Coated Tablet 10mg/80mg** [Amlodipine besylate 10mg & Atorvastatin calcium 80mg]	➢ Indication: *In patients with clinically evident coronary heart disease, atorvastatin is indicated to:* • *reduce the risk of non-fatal myocardial infarction* • *reduce the risk of fatal and non-fatal stroke* • *reduce the risk for revascularization procedures* • *reduce the risk of hospitalization for CHF* • *reduce the risk of angina*	**PFIZER (MALAYSIA) SDN. BHD.** Level 9-2, 10 & 11, Wisma Averis, Tower 2 Avenue 5, Bangsar South, No.8, Jalan Kerinchi 59200 Kuala Lumpur