Maklumat tambahan indikasi untuk upload pada laman web
Year 2016
Products Approved For Additional Indication (DCA 300 – 7 Jun 2016)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Targin Prolonged Release Tablets 10mg/5mg** [Oxycodone hydrochloride 10mg & Naloxone hydrochloride 5mg] 1.2 **Targin Prolonged Release Tablets 20mg/10mg** [Oxycodone hydrochloride 20mg & Naloxone hydrochloride 10mg] 1.3 **Targin Prolonged Release Tablets 5mg/2.5mg** [Oxycodone hydrochloride 5mg & Naloxone hydrochloride 2.5mg] 1.4 **Targin Prolonged Release Tablets 40mg/20mg** [Oxycodone hydrochloride 40mg & Naloxone hydrochloride 20mg]	➢ Indication: *Second line symptomatic treatment of patients with severe to very severe idiopathic restless legs syndrome after failure of dopaminergic therapy.* ➢ Posology: *Targin is indicated for patients suffering from RLS for at least 6 months. RLS symptoms should be present daily and during daytime (≥ 4 days/week). Targin should be used after failure of previous dopaminergic treatment. Dopaminergic treatment failure is defined as inadequate initial response, a response that has become inadequate with time, occurrence of augmentation or unacceptable tolerability despite adequate doses. Previous treatment with at least one dopaminergic medicinal product should have lasted in general 4 weeks. A shorter period might be acceptable in case of unacceptable tolerability with dopaminergic therapy.* *The dosage should be adjusted to the sensitivity of the individual patient.* *Treatment of patients with restless legs syndrome with Targin should be under the supervision of a clinician with experience in the management of restless legs syndrome.* *Unless otherwise prescribed, Targin should be administered as follows:* *<u>Adults</u>* *The usual starting dose is 5 mg/2.5 mg of oxycodone hydrochloride/naloxone hydrochloride at 12 hourly intervals.* *Titration on a weekly basis is recommended in case higher doses are required. The mean daily dose in the pivotal study was 20mg/10mg oxycodone hydrochloride/naloxone hydrochloride. Some patients may benefit from higher daily doses up to a maximum of 60 mg/30 mg oxycodone hydrochloride/naloxone hydrochloride.* *Targin tablets is taken at the determined dosage twice daily according to a fixed time schedule. While symmetric administration (the same dose*	**MUNDIPHARMA PHARMACEUTICALS SDN. BHD.** A-5-01 Level 5, Block A, PJ8 No. 23, Jalan Barat, Seksyen 8 46050 Petaling Jaya, Selangor

		mornings and evenings) subject to a fixed time schedule (every 12 hours) is appropriate for the majority of patients, some patients, depending on the individual situation, may benefit from asymmetric dosing tailored to the individual patient. In general, the lowest effective dose should be selected. *For doses not realisable/practicable with this strength other strengths of this medicinal product are available.* *<u>Children and adolescents (under 18 years)</u>* *Targin tablets is not recommended for use in children and adolescents below the age of 18 years due to a lack of data on safety and efficacy.* *<u>Elderly patients</u>* *Dosage should be adjusted to the intensity of RLS symptoms and the sensitivity of the individual patient.* *<u>Patients with impaired hepatic function</u>* *A clinical trial has shown that plasma concentrations of both oxycodone and naloxone are elevated in patients with hepatic impairment. Naloxone concentrations were affected to a higher degree than oxycodone. The clinical relevance of a relative high naloxone exposure in hepatic impaired patients is yet not known. Caution must be exercised when administering Targin to patients with mild hepatic impairment. In patients with moderate and severe hepatic impairment Targin is contraindicated.* *<u>Patients with impaired renal function</u>* *A clinical trial has shown that plasma concentrations of both oxycodone and naloxone are elevated in patients with renal impairment. Naloxone concentrations were affected to a higher degree than oxycodone. The clinical relevance of a relative high naloxone exposure in renal impaired patients is yet not known. Caution should be exercised when administering Targin to patients with renal impairment.*	