Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 381, 2 Februari 2023

Products approved for additional indication (DCA 381 – 2 February 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	DECAPEPTYL 0.1MG INJECTION [Triptorelin Acetate 100 mcg/ml (Equivalent to triptorelin 95.6 mcg/ml)]	**INDICATION :** DECAPEPTYL® 0.1 mg is indicated for downregulation and prevention of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation for assisted reproductive technologies (ART). In clinical trials DECAPEPTYL® 0.1 mg has been used in cycles where urinary and recombinant human follicle stimulating hormone (FSH) as well as human menopausal gonadotrophin (HMG) were used for stimulation. **POSOLOGY :** The dosage regimen of DECAPEPTYL® is 0.1 mg given once daily as a 1 mL subcutaneous injection. <u>Posology</u> Treatment with DECAPEPTYL should be initiated under the supervision of a physician experienced in the treatment of infertility. Treatment can be started in the early follicular phase (day 2 or 3 of the menstrual cycle) or in the mid-luteal phase (day 21-23 of the menstrual cycle or 5-7 days before expected start of menses). Controlled ovarian hyperstimulation with gonadotrophins should be started after approximately 2-4 weeks of DECAPEPTYL® treatment. Ovarian response should be monitored clinically (including ovarian ultrasound alone or preferably in combination with measurement of oestradiol levels) and the dose of gonadotrophins adjusted accordingly. When a suitable number of follicles have reached an appropriate size, treatment with DECAPEPTYL® and gonadotrophin is stopped and a single injection of hCG is administered to induce the final follicular maturation. If downregulation is not confirmed after 4 weeks (determined by ultrasound documentation of a shedded endometrium alone or preferably in combination with measurement of oestradiol levels), discontinuation of	**FERRING SDN. BHD.** 21-6, Block B Jaya One, No 72A, Jalan Universiti, 46200 Petaling Jaya, Selangor.

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		DECAPEPTYL® should be considered. The total duration of treatment is usually 4-7 weeks. When using DECAPEPTYL®, luteal phase support should be provided according to the reproductive medical centre's practice. In view of the possible effect on bone density, DECAPEPTYL therapy without add-back therapy should not exceed duration of 6 months (see section Special Warnings and Precautions for use). Patients with renal or hepatic impairment No specific dose recommendations are given for subjects with renal or hepatic impairment. A clinical study indicated that the risk of accumulation of triptorelin in patients with severe liver and renal impairment is small (see section Pharmacokinetic Properties). Paediatric population There is no relevant use of DECAPEPTYL® 0.1 mg in the paediatric population. <u>Method of administration</u> DECAPEPTYL® is intended for subcutaneous injection once daily into the lower abdominal wall. Following the first administration, it is advised that the patient be kept under medical supervision for 30 minutes to ensure there is no allergic/pseudo-allergic reaction to the injection. Facilities for the treatment for such reactions should be immediately available. The following injections may be self-administered as long as the patient is made aware of the signs and symptoms that may indicate hypersensitivity, the consequences of such a reaction and the need for immediate medical intervention. The injection site should be varied to prevent lipoatrophy. For instructions for use and handling, see section Special Precautions for Disposal.	