

Success in the treatment of infertility



Pirodal[®]

Bromocriptine



CODAL-SYNTO

Pirodal[®] 2.5mg tablets

Summary of the SPC for Pirodal®

Trade Name of the Medicinal Product:	Pirodal®
Qualitative and Quantitative Composition:	Each tablet contains 2.5 mg bromocriptine as bromocriptine mesylate.
Therapeutic indications:	Prevention or suppression of post-partum physiological lactation; Treatment of hyperprolactinaemia in males and females with hypogonadism and/or galactorrhoea; Treatment of infertile females with or without demonstrable hyperprolactinaemia; Treatment of patients with prolactin secreting adenomas, treatment of macroadenomas and as an alternative to surgical intervention in patients with microadenomas; Acromegaly; Parkinson's Disease; Premenstrual symptoms and benign breast disease.
Posology and Method of Administration:	Due to the variety of conditions, the recommended dosage regimes are variable. Irrespective of the final dosage, gradual introduction of bromocriptine to achieve the optimum response with minimal side effects is recommended. Initial dose should be given at bedtime, with dosage increments of 1.25 mg to 2.5 mg at two to three day intervals, and divided doses, until 2.5 mg twice a day is reached. Subsequent dosage increments, if needed, should be done in the same way. The maximum daily dose is restricted to 30mg/day. Paediatric population: Not appropriate for children under seven years of age. Hepatic impairment: Dosage reduction must be anticipated. Method of administration: Pirodal tablets should be taken with a meal.
Contra-indications:	Hypersensitivity; In patients with uncontrolled hypertension, hypertensive disorders of pregnancy, hypertension post- partum and in the puerperium. In the suppression of lactation or other non-life threatening indications in patients with a history of coronary artery disease, or other severe cardiovascular conditions, or symptoms / history of severe psychiatric disorders; Patients with these underlying conditions taking Pirodal for the indication of macroadenomas should only take it if the perceived benefits outweigh the potential risks; Long-term treatment.
Special Warnings and Precautions for Use:	Patients should be regularly monitored for the development of impulse control disorders: In rare cases serious adverse events, including hypertension, myocardial infarction, seizures, stroke or psychiatric disorders have been reported in post-partum women treated with bromocriptine for the inhibition of lactation; The possibility that hyperprolactinaemic patients may have a pituitary tumour should be recognised and complete investigation at specialised units to identify such patients is advisable.
Interactions with other medicinal products and other forms of interaction:	Alcohol; Erythromycin other macrolide antibiotics; Octreotide; Ergot alkaloids; Dopamine antagonists such as antipsychotics, butyrophenones, thioxanthenes and phenothiazines; Metoclopramide and domperidone; Drugs that can alter blood pressure.
Pregnancy and Lactation:	Bromocriptine should be withdrawn after the first missed menstrual period in pregnancy. It should not be administered to mothers who elect to breast feed for it inhibits lactation.
Undesirable Effects:	The occurrence of side effects can be minimized by gradual introduction of the dose or a dose reduction followed by a more gradual titration. The common side effects are headache, drowsiness and nasal congestion.
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MAH: Codal Synto Ltd.

