

Desired outcome



Fertilan[®]

Clomifene Citrate



CODAL-SYNTO

Fertilan[®] 50mg tablets

Summary of the SPC for Fertilan®

Trade Name of the Medicinal Product:	Fertilan®
Qualitative and Quantitative Composition:	Each tablet contains 50mg Clomifene citrate.
Therapeutic indications:	Treatment of ovulatory failure in women desiring pregnancy. It is indicated only for patients in whom ovulatory dysfunction is demonstrated. Other causes of infertility must be excluded before giving Fertilan 50mg tablets.
Posology and Method of Administration:	Adults only: The recommended dose for the first course of treatment is 50mg daily for five days, starting at any time in the patients who has had no recent uterine bleeding. If progestin-induced bleeding is planned, or if spontaneous uterine bleeding occurs before therapy, the regimen of 50mg daily for 5 days should be started on or about the fifth day of the cycle. When ovulation occurs at this dosage, there is no advantage to increasing the dose in subsequent cycles of treatment. If ovulation appears not to have occurred after the first course of therapy, a second course of 100mg daily (two 50mg tablets given as a single daily dose) for 5 days should be given. This course may be started as early as 30 days after the previous one. Increase of the dosage or duration of therapy beyond 100mg/day for 5 days should not be undertaken. The majority of patients who are going to respond will respond to the first course of therapy, and 3 courses should constitute an adequate therapeutic trial. If ovulatory menses have not yet occurred, the diagnosis should be re-evaluated. Treatment beyond this is not recommended in the patient who does not exhibit evidence of ovulation. Long-term cyclic therapy: Not recommended.
Contra-indications:	Liver disease or a history of liver dysfunction; Ovarian cyst; In patients with hormone-dependent tumours or in patients with abnormal uterine bleeding of undetermined origin.
Special Warnings and Precautions for Use:	Ovarian Hyperstimulation Syndrome; Ovarian enlargement and cyst formation; Blurring or other visual symptoms; Multiple Pregnancy; Ectopic Pregnancy; Uterine Fibroids; Ovarian Cancer.
Pregnancy and Lactation:	Clomifene 50mg tablets is not indicated during pregnancy. It is not known whether Clomifene citrate is excreted in human milk. Clomifene may reduce lactation.
Undesirable Effects:	Ovarian enlargement, vasomotor flushes, abdominal-pelvic discomfort (distension, bloating), nausea and vomiting, breast discomfort, visual symptoms, headache, intermenstrual spotting or menorrhagia, endometriosis and exacerbation of pre-existing endometriosis, multiple pregnancies, tumours/neoplasms, dizziness, light-headedness/ vertigo, nervous tension/insomnia, fatigue/depression, syncope/fainting, cerebrovascular accident, cerebral thrombosis, psychotic reactions including paranoid psychosis, neurological impairment, disorientation and speech disturbance, dermatitis, rash, urticaria, allergic reaction, erythema multiforme, ecchymosis and angioneurotic oedema, hair thinning and jaundice.
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MAH: Codal Synto Ltd.

