

Fertil[®]

Tablet

Description

Fertil (Clomiphene Citrate USP) is an orally administered, non-steroidal, ovulatory stimulant. Clomiphene Citrate is the first non-steroid preparation that in many patients induces ovulation which has failed. Clomiphene Citrate stimulates the increased secretion of both gonadotropins (FSH and LH), which induce the maturation of the ovarian follicle, ovulation and the subsequent normal function of the corpus luteum. It is most probably that Clomiphene Citrate stimulates the production of the releasing factor for gonadotropins in the hypothalamus, that induce the increasing secretion of FSH and LH. After oral administration, Clomiphene Citrate is readily absorbed from the gastrointestinal tract. Biological half-life in the plasma is 5-7 days. It is partly metabolised in the liver, and through the bile is excreted in the faeces. A part is reabsorbed and enters the enterohepatic recirculation pool.

Indications

Fertil is indicated for the treatment of ovulatory failure in women desiring pregnancy whose partners are fertile and potent. The following syndromes are most commonly associated with ovulatory failure: polycystic ovary syndrome, amenorrhoea with galactorrhoea, psychogenic amenorrhoea, some forms of secondary amenorrhoea of undetermined etiology, and post oral contraceptive amenorrhoea. Other possible causes of infertility should be excluded before giving Clomiphene Citrate. Fertil is indicated in the treatment of menorrhagia caused by hyperplastic endometrium.

Dosage and Administration

The usual dose for the first course of Fertil is 50 mg (1 tablet) a day for 5 days in the early follicular phase of the cycle, following normal menstruation or a progestagen-induced withdrawal bleeding. Many regimes have been used, but most common begin either on day 2 or day 5. If this dose induces ovulation, there is no need to increase the dose in the following courses. If this dose induces ovulation, but pregnancy does

not occur, stimulation with Clomiphene Citrate is to be continued, but up to 6 stimulative courses. If the first course does not induce ovulation, the second course should be started with 100 mg a day (2 tablets of 50 mg taken in a single dose) for 5 days. If ovulation is not induced, 2 more stimulative courses of the same dose should be given. If the next three stimulative courses do not produce a successful result, the therapeutic trial is considered to be finished. If ovulation is induced, but pregnancy does not occur, maximum 6 courses with Fertil are recommended. However, if menstrual bleeding does not occur, the patient should be examined carefully for the possible pregnancy, and the next course of therapy should be delayed until the correct diagnosis has been determined.

Contraindications

Fertil is contraindicated during pregnancy, in patients with liver disease, ovarian cysts, bleeding of undetermined origin, and in patients with neoplasms of endometrium.

Precautions

Clomiphene Citrate is not to be used for longer maintenance therapy. If ovarian enlargement occurs, the next Fertil course is not to be given until the ovaries return to their pretreatment size and the dosage of the next course may be reduced. Fertil should be used with caution with alcoholic drinks and antidepressants. There is a minimal chance of multiple pregnancies, about which the patient should be warned.

Drug Interactions

There are no significant drug interactions with Clomiphene Citrate.

Side Effects

Clomiphene Citrate is well tolerated. However a few side effects like dizziness, headache, nausea, vomiting, depression, fatigue, insomnia, vasomotor flushing, and allergic reaction may occur. Rarely ovarian enlargement and cyst formation may occur. All these effects disappear promptly after the treatment is discontinued.

Use in Special Population

Pregnancy and lactation : Fertil should not be administered during pregnancy. It is not known whether Fertil is excreted in human milk. Because

many drugs are excreted in human milk, caution should be exercised if Fertil is administered to a nursing woman. In some patients, Fertil may reduce lactation.

Commercial Pack

Fertil® Tablet : Box containing 50 tablets in blister strip. Each tablet contains Clomiphene Citrate USP 50 mg.