

1. Name of the medicinal product

[Clomid 50mg Tablets](#)

2. Qualitative and quantitative composition

Clomifene Citrate 50mg

3. Therapeutic indications

Clomid 50mg Tablets 50mg Tablets (Clomifene Citrate BP) is indicated for the treatment of ovulatory failure in women desiring pregnancy. Clomid 50mg Tablets 50mg Tablets is indicated only for patients in whom ovulatory dysfunction is demonstrated. Other causes of infertility must be excluded or adequately treated before giving Clomid 50mg Tablets 50mg Tablets.

INFERTILITY TREATMENT OVERVIEW

Infertility is defined as a couple's inability to become pregnant after one year of unprotected intercourse in women 35 years old and younger, and for six months in women over age 35 years. In any given year, about 15 percent of couples in North America and Europe who are trying to conceive are infertile.

The fertility of a couple depends upon several factors in both the male and female partner. According to one study, among all cases of infertility in developed countries, about 8 percent can be traced to male factors, 37 percent can be traced to female factors, 35 percent can be traced to factors in both the male and female partners, and 5 percent cannot be traced to obvious factors in either partner.

When infertility occurs, the male and female partners are evaluated to determine the cause and best treatment options. If the woman is not ovulating regularly, one treatment option involves taking an oral medication, clomiphene citrate (sample brand names: Clomid or Serophene).

This topic will review the use of clomiphene in the treatment of female infertility. The evaluation of the infertile couple, as well as the causes and treatment of male infertility, are discussed separately.

OVULATION

To understand why and how clomiphene is used, it is important to have a basic understanding of normal ovulation. Normally, a woman's ovaries produce one egg every 24 to 35 days. Ovulation usually occurs about 12 to 14 days before the next menstrual period. A woman's best chance for becoming pregnant occurs around the day of ovulation and one to two days before ovulation. This would be approximately 12 to 14 days after the first day of a 28-day menstrual cycle (day 1 of the menstrual cycle is the first day of bleeding).

Women who are most likely to respond to clomiphene include those with polycystic ovary syndrome (PCOS). Women who are unlikely to respond are those with absent periods and very low estrogen levels due to low body weight or exercise, or those with high follicle-stimulating hormone (FSH) levels, an indicator of ovarian aging.

WHAT IS CLOMIPHENE?

Clomiphene is a weak estrogen-like hormone that acts on the hypothalamus, pituitary gland, and ovary to increase levels of follicle-stimulating hormone (FSH) and luteinizing hormone (LH, which is also important in the process of ovulation).

An increased level of FSH hormones improves the chances of growing an ovarian follicle that can then trigger ovulation. In women who ovulate irregularly, approximately 80 percent who take clomiphene will ovulate, and 30 to 40 percent of all women who take clomiphene become pregnant. These numbers apply to women who have taken up to three cycles of clomiphene.

Pretreatment evaluation — Before any infertility treatment begins, a woman and her partner should undergo an infertility evaluation to be sure that clomiphene is the best treatment. This evaluation may include a complete history and physical examination, a semen analysis (for men), blood testing, and other tests depending upon the individual situation.

Dosing — Clomiphene is usually started on day 3, 4, or 5 of the menstrual cycle at a dose of 50 mg (one pill) once daily for five days. The first day of bleeding is called cycle day 1. If the woman does not have regular menstrual cycles (which is usually the situation), she may be given a course of progestin medication (medroxyprogesterone acetate [sample brand name: Provera]) to induce a period. However, a recent study suggests that this may not always be necessary. In a re-analysis of the study comparing clomiphene with metformin for ovulation induction, it was observed that the pregnancy rate was higher when clomiphene was started without inducing bleeding with medroxyprogesterone acetate. By not waiting for medroxyprogesterone acetate-induced withdrawal bleeding, the time to ovulation is shorter.

Ovulation usually occurs between cycle days 14 and 19. Most fertility specialists recommend the use of an ovulation predictor kit to plan intercourse. The kit uses a urine sample to predict when ovulation is about to occur by measuring the LH level; these are available without a prescription in most pharmacies. Optimal timing of intercourse is on the day of the LH surge and the following day when ovulation occurs.

If an ovulation predictor kit is not used, the couple is advised to have intercourse every other day for one week, beginning around day 10 (10 days after the menstrual period starts). However, this requires that sperm survival in the upper genital tract is two or more days and in some instances this may not be the case.

Some healthcare providers recommend ultrasound monitoring for women undergoing clomiphene treatment. This involves inserting a thin probe into the vagina and using sound waves to view the size and number of developing follicles (which contain an egg).

Use of an ovulation predictor kit, blood testing, and/or ultrasound are not required for women using clomiphene, and testing does not improve pregnancy rates significantly. However, almost all fertility specialists recommend use of an ovulation predictor kit and/or blood testing to confirm whether ovulation occurred or not, which would affect the therapy recommendations for subsequent cycles. Some recommend ultrasound, although this requires more office visits and increases the cost of treatment.

If ovulation does not occur during the first month, the clomiphene dose is increased by 50 mg each month until ovulation occurs. There is no benefit of increasing the clomiphene dose if ovulation occurs, even if pregnancy does not occur. Nearly all pregnancies occur within the first six ovulatory cycles while using clomiphene, and there is little benefit of continuing clomiphene treatment after six unsuccessful ovulatory cycles. If this occurs it would suggest the need to evaluate other causes of infertility. Failure to achieve pregnancy when ovulation is occurring is not a "clomid failure." It usually means that other fertility issues are present, such as tubal or male factor.

Benefits — The benefit of clomiphene is that it is relatively inexpensive and can be used before other, more expensive testing (such as hysterosalpingogram or laparoscopy) or infertility treatments (eg, gonadotropin therapy, in vitro fertilization [IVF]). It does not require monitoring with ultrasound or blood hormone levels, although monitoring may be recommended in some cases. Clomiphene improves the chances of becoming pregnant for most women who ovulate irregularly, and it carries a low risk of dangerous side effects. In addition to anovulation, clomiphene is also administered in conjunction with intrauterine insemination in unexplained infertility.

Risks — Risks of clomiphene therapy include a slightly increased rate of multiple pregnancies; approximately 6 percent of women who use clomiphene have twins, while less than 0.5 percent have triplets or greater. There is a small risk of the ovaries becoming enlarged, although severe enlargement (known as ovarian hyperstimulation syndrome [OHSS]) is rare.

Common side effects of clomiphene include hot flashes, headaches, abdominal bloating and pain, nausea and vomiting, mood changes, and breast tenderness. Visual symptoms such as blurring, double vision, or seeing spots occur in 1 to 2 percent of women, and usually resolve when treatment stops.

Most studies do not show an increased risk of birth defects, miscarriage, or learning disability in children of women who took clomiphene. There is no increased risk of breast cancer or uterine cancer. There may be a slightly increased risk of ovarian cancer if more than 12 cycles of clomiphene are used.

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