Clomihead 100 Tablet

Clomiphene (100mg) Tablet

Composition

Each tablet contains:

Clomiphene Citrate – 100 mg

Excipients:

 Lactose, starch, magnesium stearate, and other suitable excipients.

Description

Clomiphene is a selective estrogen receptor modulator (SERM) used primarily for the treatment of ovulatory dysfunction in women who are trying to conceive. It stimulates ovulation by increasing the secretion of gonadotropins, which in turn stimulates the ovaries to produce mature eggs.

Indications

- Anovulatory infertility: To induce ovulation in women with anovulation (lack of ovulation) due to conditions such as polycystic ovary syndrome (PCOS), hypothalamic amenorrhea, or other causes of infertility.
- Ovulation induction: For women who are infertile and have normal or mildly abnormal hormone levels.
- Male infertility (off-label use): Clomiphene may be used in men with low sperm count or low testosterone to stimulate the pituitary gland to increase the secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which in turn can increase sperm production.

Dosage and Administration

- Adults (Females):
 - Initial dose: One 100 mg tablet per day for 5 days, typically starting on day 2, 3, or 5 of the menstrual cycle.
 - After 5 days of treatment, ovulation is monitored, and if ovulation does not occur, the dose may be increased to 150 mg per day for a subsequent cycle.
 - If ovulation occurs but pregnancy does not, additional cycles of clomiphene therapy may be attempted with dose adjustments.
- Male infertility:
 - The usual dosage for males is 25 to 50 mg per day, taken for 3-6 months depending on response.
 - Monitoring of testosterone and sperm count should be done during treatment.
- Renal and Hepatic Impairment:
 - Clomiphene should be used with caution in patients with significant liver dysfunction. It is not recommended in patients with severe liver impairment.

Mechanism of Action

Clomiphene works by binding to estrogen receptors in the hypothalamus and pituitary gland, which prevents estrogen from negatively feedback inhibiting gonadotropin release. This leads to increased secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which promotes the growth and maturation of ovarian follicles, inducing ovulation.

Contraindications

• Pregnancy: Clomiphene should not be used during pregnancy as it may cause harm to the fetus.

- Liver disease: Known or suspected liver disease or dysfunction, including cirrhosis or jaundice.
- Unexplained uterine bleeding: Clomiphene should not be used if the cause of abnormal uterine bleeding is unknown.
- Ovarian cysts: Women with certain types of ovarian cysts (e.g., non-functional ovarian cysts) should not use Clomiphene.
- Thyroid and adrenal gland dysfunction: Caution is needed in patients with thyroid or adrenal disorders.

Warnings and Precautions

- Ovarian Hyperstimulation Syndrome (OHSS): Clomiphene can lead to OHSS, a potentially life-threatening condition, especially with high doses or multiple cycles. Symptoms include abdominal pain, swelling, nausea, and shortness of breath.
- Multiple Pregnancies: Use of clomiphene increases the risk of multiple births (twins or higher-order multiples).
- Visual disturbances: Clomiphene may cause blurred vision, flashes, or spots, which could be temporary or persistent. Patients should be cautioned about performing tasks that require full visual acuity (e.g., driving).
- Liver function: Periodic liver function tests should be conducted, especially if Clomiphene is used for extended periods.
- Endometrial thickening: Prolonged use may cause abnormal changes in the uterine lining, increasing the risk of endometrial cancer in some women.

Side Effects

Common Side Effects:

- Hot flashes
- Abdominal discomfort or bloating
- Headache, dizziness
- Nausea or vomiting
- Breast tenderness
- Mood swings
- Visual disturbances (e.g., blurred vision, spots, or flashes)

- Ovarian Hyperstimulation Syndrome (OHSS)
- Multiple pregnancies (twins, triplets, etc.)
- Severe abdominal pain or pelvic discomfort
- Liver damage: jaundice, dark urine, upper right abdominal pain
- Visual impairment: sudden loss of vision or other visual disturbances

Drug Interactions

- Gonadotropins: The use of Clomiphene with gonadotropins (e.g., human chorionic gonadotropin (hCG)) may increase the risk of ovarian hyperstimulation syndrome (OHSS).
- Corticosteroids: Caution is advised when using corticosteroids with Clomiphene as they may increase the risk of fluid retention or exacerbate side effects.
- Tamoxifen: Since Clomiphene is also a selective estrogen receptor modulator, using it concurrently with tamoxifen may increase the risk of endometrial changes.

Storage

- Store at 15°C to 25°C (59°F to 77°F).
- Protect from light and moisture.
- Keep out of reach of children.

Note: Clomiphene should only be used under the supervision of a healthcare professional familiar with its indications and risks, especially regarding its use in ovulation induction and infertility treatments. If you experience any severe side effects, contact your healthcare provider immediately.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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Serious Side Effects: