Clomitab Tablets

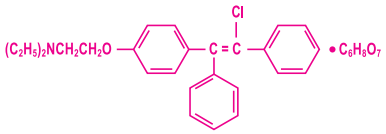
(Clomifene Tablets BP)

کلومی ٹیب گولیاں

(کلومی فین) ۵۰ ملی گرام

COMPOSITION:
Each tablet contains:
Clomifene Citrate BP ... 50mg. [BP Specs.]

DESCRIPTION: Clomifene is a estrogen-like hormone that acts on the hypothalamus, pituitary gland, and ovary to increase levels of FSH and luteinizing hormone (LH, which is also important in the process of ovulation). An increased level of these hormones improves the chances of growing an ovarian follicle that can then trigger ovulation. In women who ovulate irregularly, approximately 80 percent who take clomifene will ovulate, and 30 to 40 percent of all women who take Clomifene become pregnant. These numbers apply to women who have taken up to three cycles of Clomifene.



CLOMITAB (Clomifene Tablets BP) is an orally administered, nonsteroidal, ovulatory stimulant.

INDICATIONS:
CLOMITAB is indicated for the treatment of ovulatory dysfunction in women desiring pregnancy. Impediments to achieving pregnancy must be excluded or adequately treated before beginning **CLOMITAB** therapy. Those patients most likely to achieve success with Clomifene therapy include patients with
Polycystic ovary syndrome,
Amenorrhea-galactorrhea syndrome,
Psychogenic amenorrhea, post-oral-contraceptive amenorrhea and certain cases of secondary amenorrhea of undetermined etiology.
Properly timed coitus in relationship to ovulation is important.
CLOMITAB is indicated only in patients with demonstrated ovulatory dysfunction who meet the conditions described below:
1. Patients who are not pregnant.
2. Patients without ovarian cysts. **CLOMITAB** should not be used in patients with ovarian enlargement except those with polycystic ovary syndrome. Pelvic examination is necessary prior to the first and each subsequent course of **CLOMITAB** treatment.
3. Patients without abnormal vaginal bleeding. If abnormal vaginal bleeding is present, the patient should be carefully evaluated to ensure that neoplastic lesions are not present.
4. Patients with normal liver function.
There are no adequate or well-controlled studies that demonstrate the effectiveness of **CLOMITAB** in the treatment of male infertility.

SIDE EFFECTS & DRUG INTERACTIONS:
SIDE EFFECTS:
Clinical Trial Adverse Events. CLOMITAB, at recommended dosages, is generally well tolerated. Adverse reactions usually have been mild and transient and most have disappeared promptly after treatment has been discontinued. The following adverse events have been reported in fewer than 1% of patients in clinical trials: Acute abdomen, appetite increase, constipation, dermatitis or rash, depression, diarrhea, dizziness, fatigue, hair loss/dry hair, increased urinary frequency/volume, insomnia, light-headedness, nervous tension, vaginal dryness, vertigo, weight gain/loss.

DRUG INTERACTIONS: Drug interactions with **CLOMITAB** have not been documented.

PRECAUTIONS:
General: Oral administration of **CLOMITAB** to male rats at doses of 0.3 or 1 mg/kg/day caused decreased fertility, while higher doses caused temporary infertility. Oral doses of 0.1mg/kg/day in female rats temporarily interrupted the normal cyclic vaginal smear pattern and prevented conception.
Doses of 0.3mg/kg/day slightly reduced the number of ovulated ova and corpora lutea, while 3mg/kg/day inhibited ovulation.
Nursing Mothers: It is not known whether **CLOMITAB** is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if **CLOMITAB** is administered to a nursing woman. In some patients, **CLOMITAB** may reduce lactation.
Ovarian Cancer: Prolonged use of Clomifene Tablets BP may increase the risk of a borderline or invasive ovarian tumor.

Rev: 04-19/4

OVERDOSE:
Signs and Symptoms: Toxic effects accompanying acute overdosage of **CLOMITAB** have not been reported. Signs and symptoms of overdosage as a result of the use of more than the recommended dose during **CLOMITAB** therapy include nausea, vomiting, vasomotor flushes, visual blurring, spots or flashes, scotomata, ovarian enlargement with pelvic or abdominal pain. Oral LD_{50}: The acute oral LD_{50} of **CLOMITAB** is 1700mg/kg in mice and 5750mg/kg in rats. The toxic dose in humans is not known. Dialysis: It is not known if **CLOMITAB** is dialyzable.

Overdosage Management: In the event of overdose, appropriate supportive measures should be employed in addition to gastrointestinal decontamination.

CONTRA-INDICATIONS:
Hypersensitivity: CLOMITAB is contra-indicated in patients with a known hypersensitivity or allergy to clomifene citrate or to any of its ingredients. Pregnancy: **CLOMITAB** should not be administered during pregnancy. **CLOMITAB** may cause fetal harm. **CLOMITAB** therapy is contra-indicated in patients with liver disease or a history of liver dysfunction. Abnormal Uterine Bleeding: **CLOMITAB** is contra-indicated in patients with abnormal uterine bleeding of undetermined origin.

CLINICAL STUDIES: During clinical investigations, 7578 patients received Clomifene Tablets, some of whom had impediments to ovulation other than ovulatory dysfunction. In those clinical trials, successful therapy characterized by pregnancy occurred in approximately 30% of these patients. There were a total of 2635 pregnancies reported during the clinical trial period. Of those pregnancies, information on outcome was only available for 2369 of the cases. Table 1 summarizes the outcome of these cases. Of the reported pregnancies, the incidence of multiple pregnancies was 7.98%: 6.9% twin, 0.5% triplet, 0.3% quadruplet, and 0.1% quintuplet. Of the 165 twin pregnancies for which sufficient information was available, the ratio of monozygotic to dizygotic twins was about 1:5. Table 1 reports the survival rate of the live multiple births. A sextuplet birth was reported after completion of original clinical studies; none of the sextuplets survived (each weighed less than 400g), although each appeared grossly normal.

Table 1. Outcome of Reported Pregnancies in Clinical Trials (n = 2369)

Outcome	Total Number of Pregnancies	Survival Rate
Pregnancy Wastage		
Spontaneous Abortions	483*	
Stillbirths	24	
Live Births		
Single Births	1697	98.16%†
Multiple Births	165	83.25%†

*Includes 28 ectopic pregnancies, 4 hydatiform moles, and 1 fetus papyraceous.
† Indicates percentage of surviving infants from these pregnancies. The overall survival of infants from multiple pregnancies including spontaneous abortions, stillbirths, and neonatal deaths is 73%.

DOSAGE: A basal body temperature graph or other appropriate tests may help the patient and her physician determine if ovulation occurred. Once ovulation has been established, each course of **CLOMITAB** should be started on or about the 5th day of the cycle. Long-term cyclic therapy is not recommended beyond a total of about six cycles (including three ovulatory cycles). The majority of patients who are going to ovulate will do so after the first course of therapy. If ovulation does not occur after three courses of therapy, further treatment with **CLOMITAB** is not recommended and the patient should be reevaluated. If three ovulatory responses occur, but pregnancy has not been achieved, further treatment is not recommended. If menses does not occur after an ovulatory response, the patient should be reevaluated.

INSTRUCTIONS:
Store below 30°C.
Protect from heat, light & moisture.
Keep out of the reach of children.

PRESENTATION:
CLOMITAB 50 mg tablet is available in pack of 10's

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.
Rev: 04-19/4