

Ovajet

Clomifene Citrate BP 50 mg & 100 mg Tablet

Composition : Ovajet 50 Tablet: Each Tablet contains Clomifene Citrate BP 50 mg.

Ovajet 100 Tablet: Each Tablet contains Clomifene Citrate BP 100 mg.

Pharmacology: Clomifene Citrate is an orally administered, nonsteroidal, ovulatory stimulant. Clomifene Citrate is a drug of considerable pharmacologic potency. With careful selection and proper management of the patient, Clomifene Citrate has been demonstrated to be a useful therapy for the anovulatory patient desiring pregnancy.

Indication: Clomifene Citrate is indicated for the treatment of ovulatory dysfunction in women desiring pregnancy who meet the conditions described below: 1) Patients who are not pregnant. 2) Patients without ovarian cysts. Clomifene Citrate should not be used in patients with ovarian enlargement except in those with polycystic ovary syndrome. Pelvic examination is necessary prior to the first and each subsequent course of Clomifene Citrate 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. Impediments to achieving pregnancy must be excluded or adequately treated before beginning Clomifene Citrate 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. Once ovulation has been established, each course of Clomifene Citrate therapy 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).

Dosage and administration: Ovulation most often occurs from 5 to 10 days after a course of Clomifene Citrate. Coitus should be timed to coincide with the expected time of ovulation. Appropriate tests to determine ovulation may be useful during this time. Recommended Dosage: Treatment of the selected patient should begin with a low dose, 50mg daily (1 tablet) for 5 days. The dose should be increased only in those patients who do not ovulate in response to cyclic 50mg Clomifene Citrate. A low dosage or duration of treatment course is particularly recommended if unusual sensitivity to pituitary gonadotropin is expected, such as in patients with polycystic ovary syndrome. The patient should be evaluated carefully to exclude pregnancy, ovarian enlargement or ovarian cyst formation between each treatment cycle. If progestin induced bleeding is planned or if spontaneous uterine bleeding occurs prior to therapy, the regimen of 50mg daily for 5 days should be started on or about the 5th day of the cycle. Therapy may be started at any time in the patient who has had no recent uterine bleeding. When ovulation occurs at this dosage, there is no advantage to increasing the dose in subsequent cycles of treatment. If ovulation does not appear to occur 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 after precautions are taken to exclude the presence of pregnancy. Increasing the dosage or duration of therapy beyond 100mg/day for 5 days is not recommended. 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 Clomifene Citrate is not recommended and the patient should be re-evaluated. 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 re-evaluated. Long term cyclic therapy is not recommended beyond a total of about six cycles. Or, as directed by the registered physician.

Contraindication: It is contraindicated in patients with a known hypersensitivity to Clomifene Citrate or any other components of this product.

Precaution: Careful attention should be given to the selection of candidates for Clomifene Citrate therapy. Pelvic examination is necessary prior to Clomifene Citrate treatment and before each subsequent course.

Side effects: Clomifene Citrate at recommended dosages is generally well tolerated. Side effects are: Ovarian enlargement, vasomotor flushes, abdominal-pelvic discomfort/distention/ bloating, nausea, vomiting, breast discomfort, visual symptoms, blurred vision.

Use in Pregnancy and lactation: Clomifene should not be administered during pregnancy. It is not known whether Clomifene Citrate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if Clomifene Citrate is administered to a nursing woman.

Use in Child: There is no data available.

Drug Interaction: There is no data available.

Overdose: Signs and symptoms of overdosage include nausea, vomiting, vasomotor flushes, visual blurring, spots or flashes, scotomata, ovarian enlargement with pelvic or abdominal pain. In the event of overdose, appropriate supportive measures should be employed in addition to gastrointestinal decontamination.

Storage : Store below 30°C in a dry place.

Packing : Ovajet 50 Tablet : Each box contains 30's tablet in blister pack.

Ovajet 100 Tablet : Each box contains 20's tablet in blister pack.



Manufactured by

DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh