



CLOMIPHENE CITRATE

CLOMIPHENE CITRATE 50 mg

Presented as box with 2 Blisters containing 15 capsules per carton

DESCRIPTION

Clomiphene Citrate is an oral medication, indicated for the treatment of ovulatory dysfunction in women desiring pregnancy. Impediments to achieving pregnancy must be excluded or adequately treated before beginning CLOMIPHENE CITRATE therapy. Those patients most likely to achieve success with clomiphene 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.

INDICATIONS AND USAGE

Clomiphene 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. Clomiphene 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 clomiphene 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.

CONTRAINDICATIONS

Hypersensitivity:

Clomiphene is contraindicated in patients with a known hypersensitivity or allergy to clomiphene citrate or to any of its ingredients.

Pregnancy:

Clomiphene use in pregnant women is contraindicated, as clomiphene does not offer benefit in this population. Available human data do not suggest an increased risk for congenital anomalies above the background population risk when used as indicated. However, animal reproductive toxicology studies showed increased embryo-fetal loss and structural malformations in offspring. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risks to the fetus.

Liver Disease:

Clomiphene therapy is contraindicated in patients with liver disease or a history of liver dysfunction.

Abnormal Uterine Bleeding:

Clomiphene is contraindicated in patients with abnormal uterine bleeding of undetermined origin.

Ovarian Cysts:

Clomiphene is contraindicated in patients with ovarian cysts or enlargement not due to polycystic ovarian syndrome.

Other:

Clomiphene is contraindicated in patients with uncontrolled thyroid or adrenal dysfunction or in the presence of an organic intracranial lesion such as pituitary tumor.

PRESENTATION

50mg capsules in blister packs of 15 capsules — 2 blisters per box (30 capsules).

STORAGE

Store below 25°C. Store in the original package.