

Reomen®

Clomiphene citrate tablet

DESCRIPTION

Reomen® is a preparation of clomiphene citrate. It has mainly anti-oestrogenic effects as well as some oestrogenic effects. The mechanism of clomiphene in stimulating ovulation is unknown but is believed to be related to its anti-oestrogenic properties. Clomiphene citrate competes with oestrogen for oestrogen receptor binding sites at hypothalamus, pituitary, ovary, endometrium, vagina and cervix. It stimulates the secretion of gonadotropins, follicle-stimulating hormone (FSH) and luteinizing hormone (LH); which results in ovarian follicle maturation, followed by the preovulatory LH surge, ovulation and the subsequent development of the corpus luteum. Usefulness in male infertility is also likely related to the increases in FSH and LH secretion.

INDICATIONS

For infertility treatment of females

Reomen® is indicated in the treatment of anovulation or oligo-ovulation in patients desiring pregnancy, whose sexual partners have adequate sperm, and who have potentially functional hypothalamic-hypophyseal-ovarian systems and adequate endogenous estrogen. It is also indicated in lactational amenorrhoea, psychogenic amenorrhoea, post oral contraceptive amenorrhoea and some cases of secondary amenorrhoea of unknown origin.

For infertility treatment of males

Reomen® is indicated in the treatment of infertility in males with oligospermia and poor sperm motility.

DOSAGE AND ADMINISTRATION

For females

50 mg daily for 5 days, starting any day from second to fifth day of the menstrual cycle if bleeding occurs or at any time if the patient had no recent uterine bleeding. A smaller dose or shorter duration may be necessary for individual unusually sensitive to clomiphene, such as women with polycystic ovary syndrome. If ovulation does not occur, the dose is increased to 75 mg to 100 mg daily for five days (the next course beginning as early as thirty days after the previous course). In general, three courses of therapy are adequate to assess whether ovulation is obtainable. If ovulation has not occurred, the diagnosis should be re-evaluated. If ovulation without conception occurs, this cycle is repeated until conception or for 3 or 4 cycles. If pregnancy has not occurred after a total of about 6 cycles, further clomiphene therapy is not recommended.

For males

25 mg once daily up to 90 days. A break of 5 days after every 25 days is recommended.

Patients undergoing haemodialysis

Haemodialysis shortens serum half-life by 25-30%. In patients undergoing regular haemodialysis, a loading dose of 250 mg-1 g administered prior to dialysis and a

Elderly: As adults.

Time to peak effect

Ovulation usually occurs 4 to 10 days (average 7 days) after the last day of treatment, this period of time may vary by patient and by cycle. In rare cases, ovulation may occur as late as 14 days after the last day of the treatment.

CONTRAINDICATIONS

Pregnancy, liver insufficiency, abnormal vaginal bleeding (uterine tumour, ovarian cyst).

SIDE-EFFECTS

At the recommended dosage, adverse effects usually are rare. Incidence and severity of adverse effects tend to be related to dose and duration of treatment and are usually reversible after clomiphene therapy is discontinued. Visual disturbances, ovarian hyperstimulation, hot flushes, abdominal discomfort, occasionally nausea, vomiting, depression, insomnia, breast tenderness, headache, intermenstrual spotting, menorrhagia, endometriosis, convulsions, weight gain, rashes, dizziness, hair loss have been reported. Doses over 100 mg a day for five days have been associated with a higher incidence of side effects; patients receiving these doses should be carefully monitored. There have been rare reports of ovarian cancer with fertility drugs. But a causal relationship has not been established, because infertility itself is a primary risk factor.

PRECAUTIONS

Clomiphene citrate will only be administered under medical supervision after careful selection of patients for clomiphene therapy. Complete pelvic examination is essential prior to start of treatment and should be repeated before such subsequent course to exclude pregnancy, ovarian enlargement or ovarian cyst formation between each treatment cycle. Incidence of multiple pregnancies is increased when conception takes place during clomiphene therapy.

PHARMACEUTICAL PRECAUTIONS

Keep away from light & moisture. Keep out of reach of children.

PACKAGING

Reomen® 50 tablet : Box containing 4 strips of 5 tablets each. Each tablet contains

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

DHAKA, BANGLADESH

© REGD. TRADEMARK

M/PM00410 V04