FENALE 50 TAB

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COMPOSITION

FENALE: White uncoated scored tablets each containing 50 mg of Clomiphene Citrate IP.

USES

FENALE is indicated for the treatment of anovulation and infertility due to impaired hypothalamic pituitary function.
The best response to FENALE is generally obtained in women with evidence of follicular function and endogenous oestrogen production. These patients lack adequate cyclic stimulation of pituitary gonadotrophic function. FENALE may also be of benefit in patients with limited oestrogen production.

FENALE-50 (HALF TAB) is indicated for the treatment of male infertility. Endogenous gonadotrophin stimulation is achieved with the administration of SIPHENE FENALE-50 (HALF TAB)to subfertile male with oligospermia and asthenospermia showing normal or low gonadotrophin levels and testes biopsy showing mild germinal cell hypoplasia.

DOSAGE AND ADMINISTRATION

Female Infertility :
The recommended dose for the first treatment course of FENALE is 5Omg (one FENALE tablet) daily for five consecutive days starting within the first five days of spontaneous or induced menstrual bleeding. The commencement date of FENALE therapy is arbitrary in women who have not experienced recent uterine bleedings. Response to FENALE , suggestive of ovulation is indicated by a biphasic basal body temperature, a mid-cycle rise in LH output, an increase in serum progesterone during the presumptive mid-luteal phase or by menstrual bleeding in an amenorrhoeic patient. If ovulation occurs, but pregnancy does not result, the same dose of FENALE should be repeated in the next treatment course. If presumptive evidence of ovulation is not followed by menstrual bleeding, the possibility of pregnancy should be considered and excluded before FENALE treatment is restarted.

In the absence of ovulation, the daily dose of FENALE may be increased by increments of 50 mg each successive month to a maximum of 200 mg given as a single daily dose for five days. This dose level of FENALE should not be exceeded. If ovulation does not occur, a single i.m./s.c. injection of up to 10,000 I.U. Human Chorionic Gonadotrophin may be given 7 to 10 days after the last FENALE tablet, in order to reinforce the LH surge. If the patient wishes to conceive, coitus particularly around the expected time of ovulation is advised. A maximum of six apparently ovulatory treatment courses with the lowest effective dose of FENALE is suggested. If at this stage pregnancy has not occurred, then patients should be reinvestigated and sequential METRODIN® HP / PROFASI® therapy may be considered.

Male Infertility:
One tablet of FENALE-50 (HALF TAB)per day for 25 days continued with a rest period of 5 days for 6 to 9 months or till conception occurs.

CONTRA-INDICATIONS, WARNINGS ETC

FENALE should not be administered, to patients with active liver disease or with hereditary defect in bilirubin metabolism. FENALE therapy is precluded when an effective response cannot be obtained e.g. ovarian dysgenesis or premature menopause. Appropriate treatment should first be given for hypothyroidism, adrenocortical deficiency, hyperprolactinaemia or pituitary tumor. Other possible causes or infertility in either partner

should first be excluded. Patients with very low baseline levels of endogenous gonadotrophins and oestrogens are usually less responsive to FENALE treatment and consideration should be given to gonadotrophin METRODIN® HP / PROFASI® therapy.

Patients receiving FENALE should be instructed to report any abdominal discomfort immediately and a pelvic examination should be performed to determine whether ovarian enlargement has occurred or not. While the incidence of clinically significant hyperstimulation is low with the recommended SIPHENE dosage scheme, the presence of excessive ovarian enlargement may require the dosage scheme to be modified. Rare occurrences of lutein cyst rupture with intraperitoneal haemorrhage have been reported. Vasomotor symptoms resembling "hot flushes" may occur with FENALE. Other side effects of FENALE are generally mild, not dose-related and readily reversible on drug withdrawal. These include vomiting, breast discomfort, skin reactions (dermatitis or urticaria), dizziness and hair loss. FENALE should be withdrawn if visual disturbances occur e.g. blurring, spots or flashes (in rare cases scotomata).

The multiple pregnancy rate is approximately 8%, twins representing 90% of this figure.

Although a higher abortion rate than in a normal population has been reported, this is comparable with that in women with other fertility problems. There is no evidence that this is drug related.

Care should be taken to avoid administration of FENALE if pregnancy is suspected. Although FENALE has been shown to be embryotoxic in animals at high doses, there is no evidence to suggest that it increases the incidence of congenital malformations in humans at therapeutic levels. The incidence of congenital malformations following FENALE treatment is similar to that observed in women with other fertility problems

There is evidence that some women ovulate spontaneously for some cycles after cessation of FENALE treatment. There is no experience of acute poisoning with FENALE

PHARMACEUTICAL PRECAUTIONS
Should be stored below 25° C and protected from light and moisture.

PACKING
FENALE is packed in a box containing 20 strips of 10 tablets each.

FURTHER INFORMATION
The mode of action of FENALE at the recommended dose appears to be through competition for available oestrogen receptor sites in the hypothalamus. Oestrogen is thus displaced from sites which were responsible for the suppression of gonadotrophin releasing hormone, pituitary sacretion of FSH-and LH follows, which initiates the normal menstrual cycle.