TAMOXIT® Brand of Tamoxifen Citrate, USP Antineoplastic / Antioestrogen

DESCRIPTION:

TAMOXIT®, brand of Tamoxifen Citrate is an antineoplastic, antioestrogen agent.

PROPERTIES:

TAMOXIT® is a non-steroidal antioestrogen. It inhibits the effects of endogenous oestrogen, probably by binding with cytophasmic oestrogen receptors. It may stimulate the secretion of pituitary gonadotrophic hormones, probably by blocking the effect of oestrogens in the hypothalamus and pituitary. It may also inhibit the production or release of cellular growth factors.

PHARMACOKINETICS:

TAMOXIT® is rapidly absorbed after oral administration with a peak plasma attained within 4 - 7 hours. It is highly bounded to serum proteins (about 99%). It is extensively metabolised in the liver into pharmacologically active metabolites. Metabolites are excreted slowly in the faeces, mainly as conjugates. Small amounts are excreted in urine. **TAMOXIT®** appears to undergo enterohepatic circulation.

INDICATIONS:

- Treatment of neoplastic breast and endometrial cancer.
- Treatment of anovulatory infertility.

CONTRAINDICATIONS:

Hypersensitivity to Tamoxifen Citrate. Pregnant and nursing women.

PRECAUTIONS:

In premenopausal women and during breast disease treatment, menstruation is supressed. Notify physician if marked weakness, sleepness, mental confusion, pain or swelling of legs, shortness of breath or blurred vision occur.

ADVERSE EFFECTS:

May cause flushes, nausea, vomiting, weight gain, menstrual irregularities, vaginal bleeding, dizziness. May cause hypercalcemia in patients with bony metastases.

DOSAGE & ADMINISTRATION:

- * Breast and endometrial cancer: 10 or 20 mg twice daily.
- * Anovulatory infertility:
 - a- For regularly menstruating women: Initially, 10 mg twice daily on the second, third, fourth and fifth days of the menstrual cycle. In case of unsatisfactory results following the initial course, further courses may be given during subsequent menstrual cycles, with an increased dose of 40 mg and then 80 mg daily.
 - b- For irregularly menstruating women: The initial course may be given on any day. In case of unsatisfactory results, a subsequent course of treatment should be instaured 45 days later with an increased dosage as described above. If menstruating occurs, further courses of treatment should take place on the second day of each cycle.

DRUG INTERACTIONS:

TAMOXIT® may potentialize the anticoagulant effects of coumarin-type anticoagulants.

AVAILABILITY:

Tablets: Packs of 30 tablets each containing Tamoxifen (as Citrate) 10 mg,

Excipient q.s. 1 tablet.

Reg. No.:

Lebanon: 27595.