Tamona®

Tamoxifen Tablet

Description

Tamona is a praparation of Tamoxifen which is a non-steroidal, triphenylene based drug and displays a complex spectrum of oestrogen antagonist and oestrogen agonist like pharmacological effects in different tissues. In breast cancer patients, at the tumour level, Tamoxifen acts primarily as an antioestrogen, preventing oestrogen binding to the oestrogen receptor. Additionally Tamoxifen has been reported to lead to maintenance of bone mineral density in post-menopausal women.

Indications

Tamona is indicated for the treatment of breast cancer.

Dosage and Administration

Adults (including elderly) : The dosage range is 20 to 40 mg daily, given either in divided doses twice daily or as a single dose once daily.

Contraindication

Tamona must not be administered during pregnancy. Tamona should not be given to patients who have experienced hypersensitivity to the product or any of its ingredients.

Precautions

Menstruation is suppressed in a proportion of premenopausal women receiving Tamoxifen for the treatment of breast cancer. An increased incidence of endometrial cancer has seen reported in association with Tamoxifen treatment. The underlying mechanism is unknown, but may be related to the oestrogen-like effect of Tamona. Any patients receiving or having previously received Tamona, who report abnormal gynaecological symptoms, especially vaginal bleeding, should be promptly investigated.

A number of second primary tumors, occurring at sites other than the endometrium and the opposite breast, have been reported in clinical trials, following the treatment of breast cancer patients with Tamoxifen. No causal link has been established and the clinical significance of these observations remains unclear.

Drug Interactions

When Tamoxifen is used in combination with coumarin type anticoagulants, a significant increase in anticoagulant effect may occur. Where such co-administration is initiated, careful monitoring of the patient is recommended. When Tamoxifen is used in combination with cytotoxic agents, there is an increased risk of thromboembolic events.

Side Effects

Side effects can be classified as either due to the pharmacological action of the drug, e.g., hot flushes, vaginal bleeding, vaginal discharge, pruritus vulvae and tumour flare or as more general side effects, e.g., gastrointestinal intolerance, headache, light-headedness and occasionally fluid retention and alopecia. When such side effects are severe, it may be possible to control them by a simple reduction of dosage (within the recommended dose range) without loss of control of the disease.

Skin rashes including isolated reports of erythema multiforme, Stevens Johnson syndrome and bullous pemphigoid and rare hypersensitivity reactions, including angio-oedema have been reported. A small number of patients with bony metastases have developed hypercalcaemia on initiation of therapy.

Falls in platelet count, usually only to 80,000-90,000 per/mm^3 but occasionally lower, have been reported in patients taking Tamona for breast cancer.

A number of cases of visual disturbances including infrequent reports of corneal changes and retinopathy have been described in patients receiving Tamoxifen therapy. An increased incidence of cataracts has been reported in association with the administration of the drug. Uterine fibroids and endometrial changes including hyperplasia and polyps have been reported. Cystic ovarian swellings have occasionally been observed in premenopausal women receiving Tamoxifen.

Leucopenia has been observed following the administration of Tamoxifen, sometimes in association with anaemia and/or thrombocytopenia. Neutropenia has been reported on rare occasions; this can sometimes be severe. There is evidence of an increased incidence of thromboembolic events including deep vein thrombosis and pulmonary embolism during Tamoxifen therapy.

Tamoxifen has been associated with changes in liver enzyme levels and on rare occasions with a spectrum of more severe liver abnormalities, including fatty liver, cholestasis and hepatitis. Rarely, elevation of serum triglyceride levels, in some cases with pancreatitis, may be associated with the use of Tamoxifen.

Use in Special Populations

Pregnancy : Tamoxifen must not be administered during pregnancy. There have been a small number of reports of spontaneous abortions, birth defects and foetal deaths after women have taken Tamoxifen, although no causal relationship has been established. Reproductive toxicology studies in rats, rabbits and monkeys have shown no teratogenic potential.

Women should be advised not to become pregnant whilst taking Tamona and should use barrier or other nonhormonal contraceptive methods if sexually active. Premenopausal patients must be carefully examined before treatment to exclude pregnancy. Women should be informed of the potential risks to the foetus, if they want to become pregnant whilst taking Tamona or within two months of cessation of therapy.

Lactation : It is not known if Tamoxifen is excreted in human milk and therefore the drug is not recommended during lactation. The decision to discontinue Tamona should take into account in case of the importance of the drug to the lactating mother.

Commercial Packs

Tamona® 10 Tablet : Box containing 30 tablets in 3 x 10's Alu-Alu form packs. Each tablet contains Tamoxifen Citrate BP equivalent to 10 mg of Tamoxifen.

Tamona® 20 Tablet : Box containing 30 tablets in 3 x 10's Alu. Alu. form packs. Each tablet contains Tamoxifen Citrate BP equivalent to 20 mg of Tamoxifen.