Help when you need it

Tamoxifen-Synto®

Tamoxifen citrate

CODAL-SYNTO

Tamoxifen Synto® 10mg tablets • **Tamoxifen Synto®** 20mg tablets

Summary of SPC for Tamoxifen-Synto®

Trade Name of the Medicinal Product:	Tamoxifen-Synto®.
Qualitative and Quantitative Composition:	Each tablet contains 10mg/20mg of tamoxifen as tamoxifen citrate.
Therapeutic indications:	For the treatment of breast cancer and anovulatory infertility.
Posology and Method of Administration:	**Breast Cancer:** Adults: Daily dose is normally 20 mg. No additional benefit has been demonstrated with higher doses. Substantive evidence supporting the use of treatment with 30-40 mg per day is not available, although these doses have been used in some patients with advanced disease. **Anovulatory infertility:** Adults: Before any course of treatment, the possibility of pregnancy must be excluded. In women who are menstruating regularly, but with anovular cycles, the initial course of treatment consist of 20mg given daily on the second, third, fourth and fifth days of the menstrual cycle. If unsatisfactory basal temperature records or poor pre-ovulatory cervical mucus indicate that this initial course of treatment has been unsuccessful, further courses may be given during subsequent menstrual periods, increasing the dosage to 40mg and then to 80mg daily. In women who are not menstruating regularly, the initial course may begin on any day. If no signs of ovulation are demonstrable, then a subsequent course of treatment may start 45 days later, with dosage increased as above. If a patient responds with menstruation, then the next course of treatment is commenced on the second day of the cycle. Pediatric population: Not recommended.
Contra-indications:	Hypersensitivity; Pregnancy; Concurrent anastrozole therapy; Treatment of infertility: Patients with a personal or family history of venous thromboembolic events or a known genetic defect.
Special Warnings and Precautions for Use:	Menstruation is suppressed in a proportion of premenopausal women receiving tamoxifen for the treatment of breast cancer; Endometrial changes due to oestrogen-like effect of Tamoxifen-Synto® therapy; Patients with personal and family history of venous thromboembolism (VTE); Concomitant chemotherapy; Surgery or long term immobility; Risk of induced thrombosis; McCune Albright Syndrome (MAS); Concomitant use with inhibitors of CYP2D6; Tamoxifen-Synto® contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Interactions with other medicinal products and other forms of interactions:	Coumarin-type anticoagulants; Cytotoxic agents; Anastrozole; Rifampicin and CYP2D6 inhibitors.
Pregnancy and Lactation:	Pregnancy: Not recommended. Breast-feeding: The decision either to discontinue nursing or discontinue Tamoxifen-Synto® should take into account the importance of the drug to the mother.
Undesirable Effects:	Nausea; Fluid retention; Vaginal bleeding, vaginal discharge; Skin rash; Fatigue; Anaemia; Cataracts, retinopathy; Hypersensitivity reactions; Elevated triglycerides; Leg cramp, myalgia; Uterine fibroids; Ischaemic cerebrovascular events, headache, light headedness, sensory disturbances; Pruritus valvae, endometrial changes; Alopecia; Vomiting, diarrhea, constipation; Changes in liver enzymes, fatty liver; Thromboembolic events; Thrombocytopenia, leukopenia; Visual disturbances; Pancreatitis; Hypercalcaemia; Endometrial cancer; Interstitial pneumonitis; Cirrhosis of liver; Neutropenia, agranulocytosis; Corneal changes, optic neuropathy; Uterine sarcoma, tumour flare; Optic neuritis; Hepatitis, cholestasis, hepatic failure, hepatocellular injury, hepatic necrosis; Angioedema, Steven-Johnsons syndrome, cutaneous vasculitis, bullous pemphigoid, erythema, erythema multiforme; Endometrosis, cystic ovarian swelling, vaginal polyps; Cutaneous lupus erythematosus; Porphyria cutanea tarda.
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MAH: Codal Synto Ltd.