

In hyperprolactinemia, help her *Restore Harmony*\*

**Cabernorm**  
Cabergoline Tablets I.P. 0.5 mg



Dosage:  
0.5 mg per week  
given in one or  
two doses\*

**ABOCAL 500**

Elemental Calcium 500 mg with Vitamin D3 500 I.U. Tablets

**THYROWEL**\*

L-Tyrosine, Multivitamin & Minerals Softgel Capsules

**Thyrocal D3**\*

Calcium Citrate Malate equivalent to elemental Calcium 250mg, Vitamin D3 400 IU Tablets

Abbreviated Prescribing Information GENERIC NAME: Thyroxine Sodium Tablets I.P.

#### Thyroxine\*

**QUALITATIVE & QUANTITATIVE COMPOSITION**-Each uncoated tablet contains: Thyroxine Sodium IP Equivalent to anhydrous Thyroxine Sodium .12.5/ 25/ 50/ 62.5/ 75/ 88/ 100/ 112/ 125/ 137/ 150 mcg (Synthetic Thyroid Hormone)

**THERAPEUTIC INDICATIONS**- (1)As replacement or supplemental therapy in patients of any age or state (including pregnancy) with hypothyroidism of any etiology except transient hypothyroidism during the recovery phase of sub-acute thyroiditis resulting from thyroid dysfunction, primary atrophy or partial or total absence of the thyroid gland or from the effects of surgery, radiation or drugs with or without the presence of goitre, including sub-clinical hypothyroidism; secondary (pituitary) hypothyroidism and tertiary (hypothalamic) hypothyroidism (see CONTRAINDICATIONS AND PRECAUTIONS). (2) As a pituitary TSH suppressant in the treatment or prevention of various types of euthyroid goitres, including thyroid nodules, sub-acute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goitre and in conjunction with surgery and radioactive iodine therapy in the management of thyrotoxicosis dependent well-differentiated papillary or follicular carcinoma of the thyroid.

**PHARMACOLOGY AND METHOD OF ADMINISTRATION**-The goal of replacement therapy is to achieve and maintain a clinical and biochemical euthyroid state. The goal of suppressive therapy is to inhibit growth and/or function of abnormal thyroid tissue. The dose of thyroxine that is adequate to achieve these goals depends on a variety of factors including the patient's age, body weight, cardiovascular status, concomitant medical conditions, including pregnancy, concomitant medications, and the specific nature of the condition being treated. Hence, the following recommendations serve only as dosing guidelines. Dosing must be individualized and adjustments made based on periodic assessment of the patient's clinical response and laboratory parameters. Thyroxine is administered as a single daily dose, preferably one-half to one-hour before breakfast. Thyroxine should be taken at least four (4) hours apart from drugs that are known to interfere with its absorption. Due to the long half-life of thyroxine, the peak therapeutic effect at a given dose of thyroxine may not be attained for four to six weeks. Caution should be exercised when administering thyroxine to patients with underlying cardiovascular disease, to the elderly, and to those with concomitant adrenal insufficiency. **CONTRAINDICATIONS**-Thyroxine is contraindicated in patients with untreated subclinical (suppressed serum TSH level with normal T3 and T4 levels) or overt thyrotoxicosis of any etiology and in patients with acute myocardial infarction. Thyroxine is contraindicated in patients with uncorrected adrenal insufficiency since thyroid hormones may precipitate an acute adrenal crisis by increasing the metabolic clearance of glucocorticoids. Thyroxine is contraindicated in patients with hypersensitivity to any of the inactive ingredients in Thyroxine Tablets. Combination therapy of hyperthyroidism with levothyroidism and anti-thyroid agents is not indicated in pregnancy.

**SPECIAL WARNINGS AND PRECAUTIONS**-Thyroid hormones, including thyroxine, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects. Thyroxine should not be used in the treatment of male or female infertility unless this condition is associated with hypothyroidism. **USE IN SPECIAL POPULATIONS**-Pregnancy-Studies in women taking thyroxine sodium during pregnancy have not shown an increased risk of congenital abnormalities. Therefore, the possibility of fetal harm appears remote. Thyroxine should not be discontinued during pregnancy and hypothyroidism diagnosed during pregnancy should be promptly treated. Pregnant women on Thyroxine should have their TSH measured during each trimester. An elevated serum TSH level should be corrected by an increase in the dose of Thyroxine. Since postpartum TSH levels are similar to preconception values, the Thyroxine dosage should return to the pre-pregnancy dose immediately after delivery. A serum TSH level should be obtained six to eight weeks postpartum. Thyroid hormones cross the placental barrier to some extent as evidenced by levels in cord blood of athyreotic fetuses being approximately one-third maternal levels. Transfer of thyroid hormone from the mother to the fetus, however, may not be adequate to prevent in utero hypothyroidism. **Lactation**-Although thyroid hormones are excreted only minimally in human milk, caution should be exercised when thyroxine is administered to a nursing mother. However, adequate replacement doses of thyroxine are generally needed to maintain normal lactation. **UNDESIRABLE EFFECTS**-Adverse reactions associated with thyroxine therapy are primarily those of hypothyroidism due to therapeutic over-dosage. These include General manifestations like fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating. Central nervous system related manifestations like headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia. Cardiovascular manifestations like palpitations, tachycardia, arrhythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest. Musculoskeletal: tremors, muscle weakness. Respiratory: dyspnea. Gastrointestinal: diarrhea, vomiting, abdominal cramps, and elevations in liver function tests. Dermatologic: hair loss, flushing. Endocrine: decreased bone mineral density. Reproductive: menstrual irregularities, impaired fertility.

Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in children receiving Thyroxine therapy. Over-treatment may result in craniosynostosis in infants and premature closure of the epiphyses in children with resultant compromised adult height. Seizures have been reported rarely with the institution of thyroxine therapy. Inadequate Thyroxine dosage will produce or fail to ameliorate the signs and symptoms of hypothyroidism. Hypersensitivity reactions to inactive ingredients have occurred in patients treated with thyroid hormone products. These include urticaria, pruritus, skin rash, flushing, angioedema, various GI symptoms (abdominal pain, nausea, vomiting and diarrhea), fever, arthralgia, serum sickness and wheezing. Hypersensitivity to thyroxine itself is not known to occur.

Issued on: 15th April 2021 Source: Prepared based on full prescribing information version 5.0 dated 15th April 2021 \*Trademark of the Abbott Group of Companies

# Abbott's commitment to help women live life to the fullest

TREAT HYPOTHYROIDISM WITH

**INDIA'S NO.1** PRESCRIBED THYROXINE BRANDS

# Thyronorm\*

Thyroxine Sodium Tablets I.P.

Precise Dosing, Precise Quality, Precise Treatment



India's 1<sup>st</sup> multistrain synbiotic for vaginal microflora

# COMBINORM™

Pre & Probiotics capsules



Approved for Bacterial Vaginosis

