

SYNTHROID®
(Levothyroxine Sodium Tablets, USP)
FLINT

Indications
SYNTHROID (levothyroxine sodium) Tablets serve as specific replacement therapy for reduced or absent thyroid function of any etiology.

Contraindications
Relative contraindications include acute myocardial infarction, uncorrected adrenal insufficiency and thyrotoxicosis. (See WARNINGS)

Warnings

Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. 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.

Patients with cardiovascular diseases warrant particular attention. In such cases, low initial dosage increased slowly by small increments is indicated. Occasionally, the cardiovascular capacity of the patient is so compromised that the metabolic demands of the normal thyroid state cannot be met. Clinical judgment will then dictate either a partial restoration of thyroid status or reduction in thyroid dosage.

Symptoms associated with diabetes mellitus, adrenal insufficiency (Addison's disease), hypopituitarism and diabetes insipidus may be diminished or obscured by hypothyroidism. SYNTHROID (levothyroxine sodium) therapy may aggravate the intensity of previously obscured symptoms and require appropriate adjustment of therapeutic measures directed at these concomitant disorders.

Thyroid replacement may potentiate the effects of anti-coagulants. Such patients should have frequent prothrombin determinations to assess the need to reduce anti-coagulant dosage.

Precautions

Overdosage with any thyroid drug may produce the signs and symptoms of thyrotoxicosis. With SYNTHROID (levothyroxine sodium) Tablets, the relatively slow onset of action minimizes the risk of overdose but close observation in the weeks following institution of a dosage regimen is advised. Treatment of thyroid hyperactivity induced by oral medication is confined to interruption of therapy for a week, followed by reinstatement of daily therapy at an appropriately reduced dosage.

The 100 mcg (0.1 mg) and 300 mcg (0.3 mg) tablets of SYNTHROID (levothyroxine sodium) contain FD & C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD & C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Adverse reactions

Adverse reactions are due to overdose and are those of induced hyperthyroidism.

Dosage and administration

A final adult dosage of 100 mcg (0.1 mg) to 200 mcg (0.2 mg) of SYNTHROID (levothyroxine sodium) Tablets daily will usually restore normal thyroid function.

The concomitant appearance of other diseases, especially cardiovascular diseases, usually dictates a replacement regimen with initial doses smaller than 100 mcg/day (0.1 mg). In otherwise healthy adults with relatively recent onset of hypothyroidism, full replacement dose of 150 mcg (0.15 mg) or 200 mcg (0.2 mg) has been instituted immediately without untoward effect and with good therapeutic response. However, in view of the possible presence of subclinical disorders of the cardiovascular system or endocrinopathies, a more cautious approach is recommended.

In the elderly patient with long standing disease, evidence of myxedematous infiltration and symptomatic, functional or electrocardiographic evidence of cardiovascular dysfunction, the starting dose may be as little as 25 mcg (0.025 mg) per day. Further incremental increases of 25 mcg (0.025 mg) per day may be instituted at three to four week intervals depending on patient response. Conversely, otherwise healthy adults may be started at higher daily dosage and raised to the full replacement dosage in two to three weeks.

In infants and children, the following dose/kg schedule is recommended: 1-6 months, 10 µg/kg; 6-12 months, 8 µg/kg; 1-5 years, 6 µg/kg; 5-10 years, 4 µg/kg; 10-15 years, 3 µg/kg; 15-20 years, 2.5 µg/kg.

How supplied

SYNTHROID (levothyroxine sodium) Tablets are supplied as scored, color-coded tablets in 6 concentrations: 25 mcg (0.025 mg)—orange... 50 mcg (0.05 mg)—white... 100 mcg (0.1 mg)—yellow... 150 mcg (0.15 mg)—blue... 200 mcg (0.2 mg)—pink... 300 mcg (0.3 mg)—green.

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Reference:

1. Wartofsky L, Burman KD: Hypothyroidism, in Conn HF (ed): *Current Therapy*. Philadelphia, WB Saunders Company, 1979, pp 469-473.

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the high volume in obstetrics. (They happen to be taking care of a group with increased numbers of child-bearing women and children.) At the same time, one could look at Table 1 and express the feeling that the residency trained group is not meeting certain goals as far as visits in the hospital, at home, in the emergency room, and in extended care facilities.

Rather than using the information in this paper as a prototype of what recently trained family physicians do, it would pay to ask questions of what our ideal family physicians could be doing in the not too distant future. We should avoid attaching national significance to this limited study.

William Reichel, MD
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Erratum

An inadvertent oversight was made with respect to Figure 2 in the recently published paper by Dr. Ernest Weymuller entitled "Evaluation of Neck Masses" in the December 1980 issue of this journal.

Zone B of this figure was misplaced in the key for differential diagnosis of neck masses by age groups and anatomic location. In order to clarify and correct this oversight, the corrected key is shown here.

		Key to Figure	
Zone	Child	Adult	
A	Branchial cyst	Metastatic carcinoma from upper aerodigestive tract	
	Dermoid cyst	Primary tumor of parotid or submaxillary gland	
	Thyroglossal cyst	Inflammatory node (acute or chronic including tuberculosis)	
	Nonspecific lymphadenopathy	Zenker diverticulum (rare)	
	Lymphoma	Laryngocele (rare)	
B	Infectious disease (pharyngitis, dental abscess, tuberculosis, cat scratch disease)	Carotid artery aneurysm (rare)	
	Infectious lymphadenopathy (pharynx, adenoids, scalp)	Chemodectoma (rare)	
	Lymphoma	Lymphoma	
	Neurofibroma	Nasopharyngeal tumor	
		Local skin infection	
C	Cystic hygroma	Neurofibroma	
	Thyroid lesion	Thyroid lesion	
	Branchial cyst or sinus	Metastatic carcinoma (laryngeal, pulmonary, gastrointestinal)	
	Lymphoma	Aneurysm of the aorta or great vessels	

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