Leroid

Levothyroxine Sodium BP 25mcg & 50mcgSoft Gelatin Capsule

Composition : Leroid 25 Soft Capsule : Each Soft Gelatin Capsule Contains Levothyroxine Sodium BP 25mcg.
Leroid 50 Soft Capsule : Each Soft Gelatin Capsule Contains Levothyroxine Sodium BP 50mcg.
Pharmacology : Levothyroxine is a synthetic form of the thyroid hormone, thyroxine (T_4, a tetra-iodinated tyrosine derivative) that is made and released by the thyroid gland. In the liver and kidney, T_4 is converted to T_3, the active metabolite.
Indication : It is indicated for the treatment of- *Hypothyroidism*: As replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute-thyroiditis. Primary (thyroidal), secondary (pituitary), tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. **Pituitary TSH Suppression :** In the treatment or prevention of various types of euthyroid goiters, subacute or chronic lymphocytic thyroiditis (Hashimoto's thyroiditis), multinodular goiter and as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.
Dosage and Administration : Levothyroxine Sodium Capsules as single daily oral dose, on an empty stomach, one-half to one hour before breakfast. Levothyroxine Sodium Capsules at least 4 hours before or after drugs known to interfere with Levothyroxine Sodium capsules absorption. Swallow Levothyroxine Sodium Capsules whole, do not cut, crush or chew. **Primary Hypothyroidism in Adults and in Adolescents** in Whom Growth and Puberty are Complete. Start LEROID at the full replacement dose in otherwise healthy, non-elderly individuals who have been hypothyroid for only a short time (such as a few months).The average full replacement dose of LEROID is approximately 1.6 mcg per kg per day (for example: 100-125 mcg per day for a 70 kg adult). **Adjust the dose** by 12.5 to 25 mcg increments every 4 to 6 weeks until the patient is clinically euthyroid and the serum TSH returns to normal. Doses greater than 200 mcg per day are seldom required. An inadequate response to daily doses greater than 300 mcg per day is rare and may indicate poor compliance, malabsorption, drug interactions, or a combination of these factors. **For elderly patients** or patients with underlying cardiovascular disease, start with a dose of 12.5 to 25 mcg per day. Increase the dose every 6 to 8 weeks, as needed, until the patient is clinically euthyroid and the serum TSH returns to normal. The full replacement dose of LEROID may be less than 1 mcg per kg per day in **elderly patients**. In patients with severe longstanding hypothyroidism, start with a dose of 12.5 to 25 mcg per day. **Adjust the dose** in 12.5 to 25 mcg increments every 2 to 4 weeks until the patient is clinically euthyroid and the serum TSH level is normalized. **Secondary or Tertiary Hypothyroidism** Start LEROID at the full replacement dose in otherwise healthy, non-elderly individuals. Start with a lower dose in elderly patients with underlying cardiovascular disease or patients with severe longstanding hypothyroidism as described above. Serum TSH is not a reliable measure of LEROID dose adequacy in patients with secondary or tertiary hypothyroidism, and should not be used to monitor therapy. Use the serum free-T4 level to monitor adequacy of therapy in this patient population. Titrate LEROID dosing per above instructions until the patient is clinically euthyroid and the serum free-T4 level is restored to the upper half of the normal range. **Pediatric Dosage** - Congenital or Acquired Hypothyroidism Only administer LEROID to **pediatric patients 6 years and older** who are able to swallow an intact capsule.
The recommended daily dose of LEROID in pediatric patients with hypothyroidism is based on body weight and changes with age as described in Table 1. Start LEROID at the full daily dose in most pediatric patients. Start at a lower dose in children at risk for Hyperactivity (see below). Monitor for clinical and laboratory response
Daily dose per kg body weight :

Table 1: **LEROID Capsule** Dosing Guidelines for Pediatric Hypothyroidism

Age	Daily Dose per Kg Body Weight
6-12 years	4-5 mcg/kg/day
Greater than 12 years but growth and puberty incomplete	2-3 mcg/kg/day
Growth and puberty complete:	1.6 mcg/kg/day

The dose should be adjusted based on clinical response and laboratory parameters. Or, as directed by the registered physician.
Contraindication : Untreated subclinical or overt thyrotoxicosis of any etiology and acute myocardial infarction.
Precaution : Levothyroxine has a narrow therapeutic index. so, careful dosage titration is necessary to avoid the consequences of over- or under-treatment. Caution is needed when administering Levothyroxine to patients with cardiovascular disorders.
Side effects : Common side effecis are Fatigue, weight loss, heat intolerance, headache, anxiety, tremors, muscle weakness, arrhythmias, dyspnea. diarrhea, hair loss etc.
Use in Pregnancy and Lactation : Pregnancy-Category A. Pregnancy may increase Levothyroxine requirements. *Nursing Mother*- Although thyroid hormones are excreted only minimally in human milk, caution should be exercised when it is administered to a nursing woman. However, adequate replacement doses of Levothyroxine are gernerally needed to maintain normal lactation.
Use in child : see dosage and administration.
Drug Interaction : Concurrent use of tri/tetracyclic antidepressants and Levothyroxine may increase the therapeutic and toxic effects of both drugs, possibly due to increased receptor sensitivity to catecholamines. Toxic effects may include increased risk of cardiac arrhythmias and CNS stimulation,onset of action of tricyclics may be accelerated. Administration of sertraline in patients stabilized on Levothyroxine may result in increased Levothyroxine requirements. Addition of Levothyroxine to antidiabetic or insulin therapy may result in increased antidiabetic agent or insulin requirements. Careful monitoring of diabetic control is recommended, especially when thyroid therapy is started, changed or discontinued. Serum digitalis glycoside levels may be reduced in hyperthyroidism or when the hypothyroid patients is converted to the euthyroid state. Therapeutic effect pf digitalis glycosides may be reduced.
Overdose : The signs and symptoms of overdose are those of hyperthyroidism agitation, confusion, irritability, hyperactivity, headache, sweating, mydriasis, tachycardia, arrhythmias, tachypnoea, pyrexia, increased bowel movements and convulsions. Cerebral embolism, shock, coma, and death have been reported.
Treatment of overdose : Levothyroxine Sodium should be reduced in dose or temporarily discontinued if signs or symptoms of overdosage occur. Treatment is symptomatic.
Storage : Store below 30°C in a dry place.
Packing : Leroid 25 Soft Capsule : Each box contains 60 Soft Capsules in blister pack.
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Manufactured by
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