

Composition : Leroid 25 Tablet : Each Tablet Contains Levothyroxine Sodium 25 mcg as Levothyroxine Sodium Pentahydrate BP.

Leroid 50 Tablet : Each Tablet Contains Levothyroxine Sodium 50 mcg as Levothyroxine Sodium Pentahydrate BP.

Pharmacology : Levothyroxine is a synthetic form of the thyroid hormone, thyroxine (T₄, a tetra-iodinated tyrosine derivative) that is made and released by the thyroid gland. In the liver and kidney, T₄ is converted to T₃, 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 : In order to avoid irregular absorption leroid tablets should be taken preferably at a fixed time on an empty stomach. Concomitant intake of food may decrease the absorption of Levothyroxine. Dosing must be individualized and adjustments to be made based on periodic assessment of the patients clinical response and laboratory parameters. Adult Dosage : Initial starting dose: 25-50 mcg/day, with gradual increments in dose at 6-8 week intervals, as needed. The Levothyroxine Sodium dose is generally adjusted in 12.5-25 mcg increments until the patient with primary hypothyroidism is clinically euthyroid and the serum TSH has normalized. In patients with severe hypothyroidism: Initial dose is 12.5-25 mcg/day with increases of 25 mcg/day every 2-4 weeks, accompanied by clinical and laboratory assessment, until the TSH level is normalized. In patients with secondary (pituitary) or tertiary (hypothalamic) hypothyroidism: Levothyroxine Sodium dose should be titrated until the patient is clinically euthyroid and the serum free - T₄ level is restored to the upper half of the normal range. For patients older than 50 years or for patients under 50 years of age with underlying cardiac disease: An initial dose of 25-50 mcg/day is recommended with gradual increments in dose at 6-8 week intervals. Pediatric Dosage : Newborns: The recommended starting dose is 10-15 mcg/kg/day. A lower starting dose should be considered in infants at risk for cardiac failure and the dose should be increased in 4-6 weeks as needed based on clinical and laboratory response to treatment. In infants with very low (<5 mcg/dL) or undetectable serum concentrations, the recommended initial starting dose is 50mcg/day of Levothyroxine Sodium. Infants and Children: In children with chronic or severe hypothyroidism, initial dose of 25 mcg/day with increments of 25 mcg every 2-4 Weeks until the desired effect is achieved. Hyperactivity in an older child can be minimized if the starting dose is one-fourth of the recommended full replacement dose and the dose is then increased on a weekly basis by an amount equal to one-fourth the full-recommended replacement dose until the full recommended replacement dose is reached.

Daily dose per kg body weight :

0-3 months: 10-15 mcg/kg/day

3-6 months: 8-10 mcg/kg/day

6-12 months: 6-8 mcg/kg/day,

1-5 years: 5-6 mcg/kg/day,

6-12 years: 4-5 mcg/kg/day,

>12 years but growth and puberty incomplete: 2-3 mcg/kg/day Growth and puberty complete: 1.7 mcg/kg/day.

Leroid Tablet



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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 effects 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 generally 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 of 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 Tablet : Each box contains 90's tablets in blister pack.

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