

Lupin receives sANDA approval for Levothyroxine Sodium Tablets

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It is a generic equivalent of UNITHROID®



Lupin has announced that it has received approval for its sANDA for Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg, from the United States Food and Drug Administration (U.S. FDA), to market a generic equivalent of UNITHROID® 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg, manufactured by Jerome Stevens Pharmaceuticals Inc.

Lupin's Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg was originally approved on January 18, 2019 as generic equivalent of SYNTHROID® 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg, manufactured by ABBVIE Inc.

With this sANDA approval, Lupin's Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg are now AB rated (therapeutically equivalent) with Reference Listed Drugs, SYNTHROID® and UNITHROID®.

Lupin's Levothyroxine Sodium Tablets are indicated for:

- **Hypothyroidism:** As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
- **Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression:** As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer Levothyroxine Sodium Tablets USP (RLD: UNITHROID® and SYNTHROID®) had annual sales of approximately USD 2581 million in the US (IQVIA MAT June 2019).