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Lupin receives sANDA approval from USFDA for Levothyroxine Sodium Tablets

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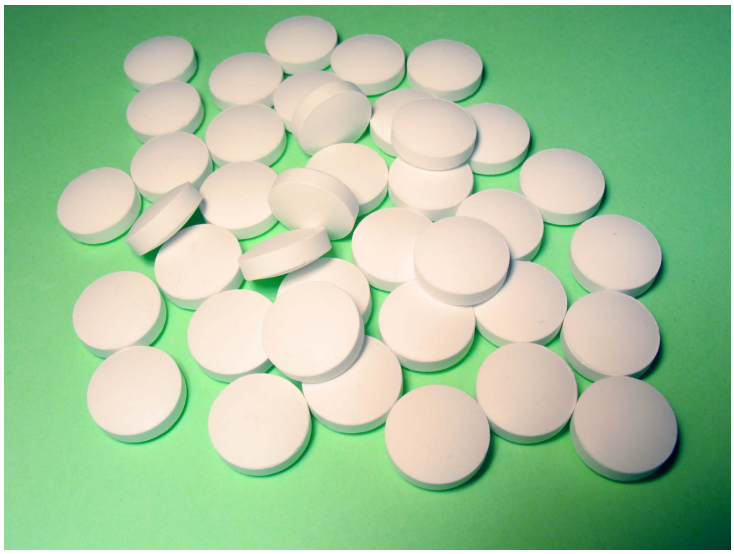
It is a generic equivalent of SYNTHROID® manufactured by ABBVIE Inc.



Lupin has announced the approval for its sANDA for Levothyroxine Sodium Tablets USP from the USFDA to market a generic equivalent of LEVOXYL® 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 King Pharmaceuticals Research and Development LLC.

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® manufactured by ABBVIE Inc.

Earlier, Lupin also received sANDA approval dated September 19, 2019 for its 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® manufactured by Jerome Stevens Pharmaceuticals 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®, UNITHROID® and LEVOXYL® and are the only product approved with FDA's new Narrow Therapeutic Index guidance for Levothyroxine.

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