

Status of Levothyroxine Products in Canada

ISSUE

The United States Food and Drug Administration (USFDA) has reclassified levothyroxine products as "new drugs" due to potential problems with potency and stability.

What is the Status of Levothyroxine Products in the USA?

On August 14, 1997, the FDA announced in the Federal Register that orally administered levothyroxine sodium drug products are "new drugs" and that manufacturers who wish to continue marketing these products must submit a new drug application for approval. The FDA based its decision on a history of potency and stability problems with levothyroxine sodium products. The notice stated that after August 14, 2000, any unapproved Levothyroxine sodium drug product on the market would be subject to regulatory action by the FDA. On April 26, 2000, the FDA extended the deadline to August 14, 2001. As noted in the FDA Talk Paper issued July 12, 2001 on this subject, there was no public health emergency in the US that required immediate action. Subsequently, the US-FDA approved Synthroid on July 24, 2002.

What is the Status of Levothyroxine Products in Canada ?

Levothyroxine sodium products currently used in Canada, have been on the Canadian market since the 1950's.

In response to the issues raised regarding the quality of levothyroxine sodium tablets, in August 2001, Health Canada analysed a representative sampling of marketed levothyroxine sodium products taken orally in Canada for potency and content uniformity, and reviewed company records regarding quality matters such as stability, recalls, and complaints. The study generated by Health Canada's laboratories revealed that all tested lots of the marketed levothyroxine sodium products taken orally complied with the established standards for potency. Health Canada also investigated its Canadian database from 1968 until October 2002 for instances of adverse events reported with the use of levothyroxine sodium. There were 7 reports of lack of efficacy and /or hypothyroidism

There is no public health emergency that requires immediate action for the levothyroxine sodium products on the market in Canada. Health Canada's investigation has shown that there was no indication of a quality concern with Synthroid® Tablets (marketed by Abbott Laboratories) and Eltroxin® Tablets (marketed by GlaxoSmithKline) in Canada. Accordingly, patients are advised to continue using their medication under the supervision of their doctors. Levothyroxine sodium has a narrow therapeutic range and is titrated in very small increments until the dose is optimized for the patient. The information provided below could help patients who are prescribed Levothyroxine products:

What should you do if you are on Levothyroxine Therapy?

1. Notify your physician if you are allergic to any foods or medicines, are pregnant or intend to become pregnant, are breast-feeding or are taking any other medications, including prescription and over-the-counter preparations.

2. Notify your physician of any other medical conditions you may have, particularly heart disease, diabetes, clotting disorders, and adrenal or pituitary gland problems. Your dose of medications used to control these other conditions may need to be adjusted while you are taking Levothyroxine. If you have diabetes, monitor your blood and/or urinary glucose levels as directed by your physician and immediately report any changes to your physician. If you are taking anticoagulants (blood thinners), your clotting status should be checked frequently.
3. Use Levothyroxine only as prescribed by your physician. Do not discontinue or change the amount you take or how often you take it, unless directed to do so by your physician.
4. The Levothyroxine in your prescribed product is intended to replace a hormone that is normally produced by your thyroid gland. Generally, replacement therapy is to be taken for life, except in cases of transient hypothyroidism, which is usually associated with an inflammation of the thyroid gland (thyroiditis).
5. Take Levothyroxine tablets in the morning on an empty stomach, at least one-half hour before eating any food.
6. It may take several weeks before you notice an improvement in your symptoms.
7. Notify your physician if you experience any of the following symptoms: rapid or irregular heartbeat, chest pain, shortness of breath, leg cramps, headache, nervousness, irritability, sleeplessness, tremors, change in appetite, weight gain or loss, vomiting, diarrhea, excessive sweating, heat intolerance, fever, changes in menstrual periods, hives or skin rash, or any other unusual medical event.
8. Notify your physician if you become pregnant while taking Levothyroxine. It is likely that your dose of Levothyroxine will need to be increased while you are pregnant.
9. Notify your physician or dentist that you are taking Levothyroxine prior to any surgery.
10. Partial hair loss may occur rarely during the first few months of Levothyroxine therapy, but this is usually temporary.
11. Levothyroxine should not be used as a primary or adjunctive therapy in a weight control program.
12. Keep Levothyroxine out of the reach of children. Store Levothyroxine away from heat, moisture, and light.

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Therapeutic Products Directorate Direction des produits thérapeutiques

Health Products and Food Branch Direction générale des produits de santé et des aliments