



Pfizer Inc
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U.S. Pharmaceuticals

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Dear Health Care Provider/Advocacy Group/Customer:

Pfizer is pleased to announce that LEVOXYL® (levothyroxine sodium), a prescription medicine approved to treat hypothyroidism and treat or prevent certain types of goiter, will be available in retail pharmacies in the United States on approximately March 3, 2014.

Patients and pharmacists should resume obtaining LEVOXYL through their regular channels. If pharmacies do not have a supply of LEVOXYL, they should contact Pfizer customer service at 1-800-533-4535, and Pfizer will work with pharmacists and their designated wholesalers to drop-ship LEVOXYL.

We are also excited to announce that Pfizer will be offering eligible patients a 30-day free trial of LEVOXYL. The 30-day free trial offer voucher is available for download at www.LEVOXYL.com. Terms and conditions apply (please see terms and conditions on the following page).

Frequently Asked Questions:

Why was LEVOXYL recalled?

Pfizer stopped shipping LEVOXYL in February 2013 to investigate reports from pharmacists and patients of an uncharacteristic odor that appeared a few days after a bottle had been opened. A thorough investigation determined that the source of the odor was an oxygen-absorbing canister that had been packaged with some bottles. The company conducted a careful assessment and concluded that the odor was not likely to cause any adverse health consequences. However, the company discussed the situation with the U.S. Food and Drug Administration and decided, out of an abundance of caution, to voluntarily recall LEVOXYL to the retail level.

Why is LEVOXYL available again?

Pfizer has corrected the issue with the oxygen-absorbing canister and has resumed manufacturing of LEVOXYL. We anticipate that LEVOXYL will be back in pharmacies on approximately March 3, 2014.

How can a patient obtain LEVOXYL if the pharmacy doesn't have it in stock?

If pharmacies do not have a supply of LEVOXYL, patients should contact Pfizer customer service at 1-800-533-4535, and we will work with pharmacists and their designated wholesalers to drop-ship LEVOXYL.

Important Safety Information

WARNING: Thyroid hormones, including LEVOXYL, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

LEVOXYL is contraindicated in patients with untreated subclinical or overt thyrotoxicosis of any etiology, acute myocardial infarction, or uncorrected adrenal insufficiency. LEVOXYL is contraindicated in patients with hypersensitivity to any of its inactive ingredients.

LEVOXYL should not be used in patients with nontoxic diffuse goiter or nodular thyroid disease if serum TSH level is already suppressed. If the TSH is not suppressed, LEVOXYL should be used with caution and monitoring for evidence of hyperthyroidism.

LEVOXYL should not be used for the treatment of male or female infertility unless this condition is associated with hypothyroidism.

LEVOXYL has a narrow therapeutic index. Careful dosage titration is necessary to avoid the consequences of over- or under-treatment such as effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, emotional state, gastrointestinal function, and glucose and lipid metabolism.

Decreased bone mineral density (BMD) has been associated with long term LEVOXYL therapy in women. It is recommended that LEVOXYL be given in the minimum dose necessary to achieve the desired response.

Please see additional Important Safety Information and Indications on following page and accompanying full Prescribing Information.


Levoxyl[®]
levothyroxine sodium tablets, USP

Important Safety Information (cont'd)

LEVOXYL® (levothyroxine sodium) should be initiated at lower doses in the elderly and in patients with cardiovascular disorders.

Many drugs affect thyroid hormone pharmacokinetics and metabolism. Thyroid hormones also affect the pharmacokinetics and action of other drugs. The prescriber should be aware of this fact and should consult appropriate reference sources.

Acute massive overdosage of LEVOXYL may be a life-threatening emergency. Symptomatic and supportive therapy should be instituted immediately.

Adverse reactions associated with LEVOXYL are primarily those of hyperthyroidism due to therapeutic overdosage: fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating, headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia, tremors, muscle weakness, palpitations, tachycardia, arrhythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest, dyspnea, diarrhea, vomiting, abdominal cramps, hair loss, flushing, menstrual irregularities, impaired fertility, and rarely seizures. Also in children: pseudo tumor cerebri, slipped capital femoral epiphysis; overtreatment may result in craniosyntosis, and premature closure of the epiphyses.

When LEVOXYL was not taken with water the following adverse events have been reported: choking, gagging, tablet stuck in throat and dysphagia.

Indications

LEVOXYL is indicated for hypothyroidism—as replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include: primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism.

LEVOXYL is indicated for pituitary TSH suppression—in the treatment or prevention of various types of euthyroid goiters including thyroid nodules, 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.

Kind regards,
Pejman Azarmina, MD
Director of Medical Affairs
Pfizer Inc.

Terms and Conditions

By redeeming this free trial voucher, you acknowledge that you currently meet the eligibility criteria and comply with the terms and conditions described below:

- You will receive a 30-day supply of LEVOXYL. Only 1 voucher per person may be redeemed under this program
- Voucher must be presented to your pharmacist along with a valid prescription for LEVOXYL
- Voucher good for one time only
- **The voucher will be accepted only at participating pharmacies**
- No membership fees
- No claim for reimbursement for product dispensed pursuant to this voucher may be submitted to any third party payor. Federal and state health care program beneficiaries are not eligible for this voucher
- This free trial voucher is not valid for Massachusetts residents whose prescriptions are covered in whole or in part by third party insurance, or where otherwise prohibited by law
- This free trial voucher cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription
- **This free trial is not health insurance**
- Offer good only in the U.S. and Puerto Rico
- Only new patients may use this voucher. By redeeming this voucher, you certify that you are not currently using LEVOXYL. This voucher is not transferable
- Pfizer reserves the right to rescind, revoke, or amend this free trial voucher without notice
- This free trial voucher expires 12/31/14
- Patients must be 18 or older
- For questions regarding reimbursement, please call 1-800-422-5604, or write: Pfizer, ATTN: LEVOXYL, PO Box 2246, Morrisville, PA 19067-8025. www.pfizer.com
- Average savings for all patients is approximately \$15

Please see additional Important Safety Information on previous page and accompanying full Prescribing Information.

