

BRAND NAME: UNITHROID® DIRECT TABLETS

IMPORTANT NOTE: The following information is intended to supplement, not substitute for, the expertise and judgment of your physician, pharmacist or other healthcare professional. It should not be construed to indicate that use of the drug is safe, appropriate, or effective for you. Consult your healthcare professional before using this drug.

WARNING: This medication should not be used either alone or in combination with diet pills to treat obesity or for weight loss because serious, even life-threatening, effects could occur. Large doses of this medication, especially with diet pills, may cause symptoms of toxicity. See the Side Effects and Overdose sections for more information.

USES: Levothyroxine is used to replace the hormone that is normally produced by the thyroid gland for a condition known as hypothyroidism. It is important to have adequate levels of thyroid hormone in your bloodstream in order for various organ systems in your body to function properly. This medication is used to treat other types of thyroid disorders as well (e.g. certain types of goiters, thyroid nodules, thyroiditis and thyroid cancer).

HOW TO USE: Take this medication on an empty stomach with a full glass of water 1 hour before or 2 hours after a meal. It is usually taken as a single daily dose before breakfast. For children who cannot swallow whole tablets, crush the tablet and mix in 1 or 2 teaspoons (5 or 10 ml) of water and give using a spoon or dropper as soon as possible after preparation. Do not store the mixture for later use. Do not mix crushed tablets in soybean infant formula. Consult your pharmacist for more information. Your doctor may need to adjust your dosage based on your medical condition, your response to therapy and your laboratory test results. Do not stop taking this medication without consulting with your doctor. Replacement therapy is usually taken for life. It may take several weeks before you notice an improvement in your symptoms.

SIDE EFFECTS: Symptoms of low thyroid levels include fatigue, muscle aches, constipation, dry skin, weight gain, slow heart rate, sensitivity to cold, or dry brittle hair that tends to fall out easily. These symptoms should disappear as your body adjusts to the medication. If they persist or become bothersome, notify your doctor promptly. Headache, nervousness, trembling, sweating, increased appetite, diarrhea, weight loss or insomnia may occur. If any of these effects persist or worsen, notify your doctor promptly. In rare instances, some hair loss may occur during the first few months of starting this drug. This effect is usually temporary as your body adjusts to this medication. If this effect persists or worsens, notify your doctor promptly. Tell your doctor immediately if you have any of these unlikely but serious side effects: chest pain, rapid or irregular heartbeat, shortness of breath. Tell your doctor immediately if you have any of these very unlikely but serious side effects: seizures. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS: This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: overactive thyroid conditions (e.g. thyrotoxicosis), a heart attack (acute myocardial infarction), adrenal gland problems (e.g. uncorrected adrenal insufficiency). Do not use thyroid drugs for weight control. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart problems (e.g. hypertension, congestive heart failure, arrhythmias, coronary artery disease), diabetes, male or female infertility problems, bone loss disease (e.g. osteoporosis), or other hormone disorders (e.g. hypothalamic/pituitary hormone deficiencies, autoimmune polyglandular

syndrome), other thyroid problems (e.g. nontoxic diffuse goiter, nodular thyroid disease), blood clotting disorders, any allergies. Notify your doctor or dentist that you are taking this medication prior to any surgery. Caution is advised when using this drug in children because overuse may reduce the child's future adult height. Consult your doctor for details. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug. Current information shows that this drug may be used during pregnancy. Tell your doctor if you are pregnant because your dose will have to be adjusted. Small amounts of this drug pass into breast milk. Consult your doctor before breast-feeding.

OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: excessive sweating, extreme nervousness, irregular heartbeat, chest pain, seizures.

NOTES: Laboratory and/or medical tests (e.g. thyroid function tests) should be done periodically to monitor the effectiveness of this medication. Inform your doctor if you change to a different brand of thyroid hormone.

MISSED DOSE: If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up. Call your doctor if you miss 2 or more doses in a row.

STORAGE: Store at room temperature (77 degrees F or 25 degrees C) away from light and moisture. Brief storage between 59 and 86 degrees F (15 and 30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

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If you have any questions about your medication, please contact one of our pharmacists at 800-662-0479.