

PRONUNCIATION: (IN-sue-lin DET-a-meer)

COMMON BRAND NAME(S): **Levemir**

HOW TO USE: Read the Patient Information Leaflet before you start using this insulin and each time you get a refill. If you have any questions, consult your doctor or pharmacist. This insulin must be injected, usually once or twice daily. Insulin detemir is usually injected with the evening meal or at bedtime. If you are using it twice a day, inject your first dose in the morning and your second dose with the evening meal, at bedtime, or 12 hours after the morning dose, as directed by your doctor. Learn all preparation and usage instructions, including how to measure the correct dose, how to inject this medication properly, and how to self-manage your diabetes (e.g., monitoring blood sugar, recognizing and treating high/low blood sugar). Your health care professional will teach you how to use this medication. If you have any questions, consult your doctor, diabetes educator, or pharmacist. Wash hands before measuring and injecting insulin. Before using, warm this drug to room temperature if it has been refrigerated. Do not inject cold insulin because this can be painful. The insulin container you are currently using can be kept at room temperature. The length of time you can store it at room temperature depends on the product. Consult your pharmacist. (See also Storage section.) Do not shake the container. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. Insulin detemir solution should be clear and colorless. Before injecting each dose, clean the injection site with rubbing alcohol. It is important to change the location of the injection site daily to prevent problem areas under the skin (lipodystrophy). Do not reuse the site for 2 weeks. Inject the medication under the skin of the thigh, abdomen, or back of the upper arm. Do not inject into a vein or muscle. After pulling out the needle, apply gentle pressure on the injection site. Do not rub the area. The dosage is based on your medical condition and response to therapy. Measure each dose very carefully because even small changes in the amount of insulin may have a large effect on your blood sugar levels. Use this medication regularly as directed by your doctor to get the most benefit from it. Carefully follow the insulin treatment plan, meal plan, and exercise program your doctor has recommended. Check your urine/blood sugar as directed by your doctor. Keep track of your results and share them with your doctor. This is very important in order to determine the correct insulin dose. This product should not be mixed with any other insulin. Do not use this insulin in an infusion pump. Do not change brands/types of insulin, syringes, or needles without directions on how to do so from your doctor. Do not reuse disposable needles and syringes. Learn how to store and discard needles and medical supplies safely. Consult your pharmacist.

USES: This man-made insulin is very similar to human insulin. It has been changed so that it acts longer than regular human insulin, providing a low, steady level of insulin. It is used along with a proper diet and exercise program to control high blood sugar in people with diabetes. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems. Proper control of diabetes may also lessen your risk of a heart attack or stroke. Insulin detemir may be used in combination with a shorter-acting insulin (regular), but they should not be mixed together in the same injection. In some people with diabetes, insulin may be used alone or with other diabetes drugs (e.g., sulfonylureas like glyburide). People with diabetes do not make enough insulin for their body to properly use the sugar in food. Eating a balanced diet, exercising regularly, and using your insulin as directed can help you live an active and healthy life.

SIDE EFFECTS: Injection site reactions (e.g., pain, redness, irritation) and swelling of the hands/feet may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. This medication can cause low blood sugar (hypoglycemia). This effect may

occur if you do not consume enough calories or if you have taken too much insulin. The symptoms include chills, cold sweat, blurred vision, dizziness, drowsiness, shaking, fast heartbeat, weakness, headache, fainting, tingling of the hands/feet, and hunger. It is a good habit to carry glucose tablets or gel to treat low blood sugar. If you don't have these reliable forms of glucose, quickly raise your blood sugar level by eating a quick source of sugar such as table sugar, honey, or candy, or drink a glass of orange juice or non-diet soda. Tell your doctor immediately about the reaction. To help prevent hypoglycemia, eat meals on a regular schedule, and do not skip meals. Check with your doctor or pharmacist about what you should do if you miss a meal. Too little insulin can cause symptoms of high blood sugar (hyperglycemia). Symptoms include thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, and fruity breath odor. If these symptoms occur, tell your doctor immediately. Your dosage may need to be increased. Insulin can rarely cause a mineral imbalance (low potassium level). Symptoms include muscle cramps/weakness and irregular heartbeat. If these symptoms occur, tell your doctor immediately. Your potassium level may need to be checked. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS: Before using insulin detemir, tell your doctor or pharmacist if you are allergic to it; or to other types of insulins; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Do not use this medication when you have low blood sugar (hypoglycemia). Before using this medication, tell your doctor or pharmacist your medical history, especially of: adrenal/pituitary gland problems, infection (especially with diarrhea or vomiting), kidney disease, liver disease, nerve problems (e.g., diabetic neuropathy), thyroid problems. You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar levels. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcohol while taking this medication because it can increase the risk of developing low blood sugar. During times of stress, such as fever, infection, injury or surgery, it may be more difficult to control your blood sugar. Consult your doctor because a change in your medication or how often you test your blood sugar may be required. Changes in your activity level may affect the amount of insulin you need. Tell your doctor if your insulin needs are changing. Check your blood sugar readings before and after exercise. You may need a snack beforehand. If traveling across time zones, ask your doctor about how to adjust your insulin schedule. Take extra insulin and supplies with you. The elderly may be more sensitive to the effects of this drug, especially low blood sugar. Children may be more sensitive to the effects of this drug, especially low blood sugar. Tell your doctor if you are pregnant before using this medication. If you are planning pregnancy, discuss a plan for managing your blood sugars with your doctor before you become pregnant. Your doctor may switch the type of insulin you use during pregnancy. Consult your doctor for more details. It is not known if this medication passes into breast milk. Consult your doctor before breast-feeding. Your insulin needs may change while breast-feeding.

DRUG INTERACTIONS: Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially: bupropion, pioglitazone/rosiglitazone. Many drugs can affect your blood sugar levels, making it more difficult to control your blood sugar. Before you start or stop any medication, talk with your doctor or pharmacist

about using that product safely. Some drugs that may affect your blood sugar include: certain antibiotics (e.g., sulfonamides, quinolones such as gatifloxacin/levofloxacin), antidepressants (e.g., MAO inhibitors), certain antipsychotics (e.g., olanzapine), estrogens (e.g., birth control pills), corticosteroids (e.g., prednisone), protease inhibitors (e.g., indinavir), salicylates (e.g., high-dose aspirin), "water pills" (diuretics such as thiazides), and some herbal products (e.g., gymnema, ginseng), among others. Check your blood sugar levels regularly as directed by your doctor. Tell your doctor about the results and of any symptoms of high or low blood sugar. (See also Side Effects section.) Your doctor may need to adjust your anti-diabetic medication or diet. Beta blocker medications (e.g., metoprolol, propranolol, glaucoma eye drops such as timolol) may prevent the fast/pounding heartbeat you would usually feel when your blood sugar level falls too low (hypoglycemia). Other symptoms of low blood sugar such as dizziness, hunger, or sweating are unaffected by these drugs. Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain ingredients that could affect your blood sugar. Ask your pharmacist about the safe use of those products. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

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 headache, sweating, shakiness, increased hunger, vision changes, nervousness, tiredness, seizures, loss of consciousness.

NOTES: Do not share this medication, needles, or syringes with others. It is recommended you attend a diabetes education program to understand diabetes and all the important aspects of its treatment, including meals/diet, exercise, personal hygiene, medications, and getting regular eye, foot, and medical exams. Keep all medical appointments. Laboratory and/or medical tests (e.g., liver and kidney function tests, fasting blood glucose, hemoglobin A1c, complete blood counts) should be performed periodically to monitor for side effects and response to therapy. Wear or carry identification stating that you have diabetes and are using this drug. (See Medical Alert section.)

MISSED DOSE: It is very important to follow your insulin regimen exactly. Do not miss any doses of insulin. Discuss specific instructions with your doctor now in case you miss a dose of insulin in the future.

STORAGE: Different types of insulin have different storage requirements. Therefore, it is important to learn and follow storage directions for your particular product. In general, store the unopened product in the refrigerator between 36-46 degrees F (2-8 degrees C). Once opened, the vial may be stored in the refrigerator or at room temperature below 86 degrees F (30 degrees C) in the carton to protect from light. Do not refrigerate the cartridge or pen anytime after you first use it. Once opened, store the cartridge or pen at room temperature below 86 degrees F (30 degrees C) in the carton to protect from light. Opened vials and cartridges/pens may be used for 42 days after first use if they have been stored in a clean, cool place and protected from light. Do not freeze. Discard the insulin if it has been frozen, if it is 42 days after first use, or if the insulin is past the expiration date. Consult your pharmacist about how to store your brand of insulin. Protect insulin from light, heat, and moisture. Keep all medicines away from children and pets. Keep extra supplies of insulin, syringes, and needles on hand. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

WARNING: No Information Available. Please Consult Your Health Care Provider or Pharmacist.