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Insulin detemir: Patient drug information

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(For additional information <u>see "Insulin detemir: Drug information"</u> and <u>see "Insulin detemir: Pediatric drug information"</u>)

Brand Names: US

Levemir; Levemir FlexTouch

Brand Names: Canada

Levemir FlexTouch; Levemir Penfill

What is this drug used for?

• It is used to lower blood sugar in patients with high blood sugar (diabetes).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: Acidic blood problem or low blood sugar.
 This is not a list of all drugs or health problems that interact with this drug.
 Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for

you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Allergic reactions have happened with this drug. Rarely, some reactions can be very bad or life-threatening. Talk with the doctor.
- Low blood sugar may happen with this drug. Very low blood sugar can lead to seizures, passing out, long lasting brain damage, and sometimes death. Talk with the doctor.
- Low blood potassium may happen with this drug. If not treated, this can lead to a heartbeat that is not normal, very bad breathing problems, and sometimes death. Talk with the doctor.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- Some diabetes drugs like pioglitazone or rosiglitazone may cause heart failure or make it worse in people who already have it. Using insulin with these drugs may increase this risk. If you also take one of these drugs, talk with the doctor.
- Be sure you have the right insulin product. Insulin products come in many containers like vials, cartridges, and pens. Be sure that you know how to measure and get your dose ready. If you have any questions, call your doctor or pharmacist.
- It may be harder to control blood sugar during times of stress such as fever, infection, injury, or surgery. A change in physical activity, exercise, or diet may also affect blood sugar.
- Wear disease medical alert ID (identification).
- Follow the diet and workout plan that your doctor told you about.
- Do not drive if your blood sugar has been low. There is a greater chance of you having a crash.
- Check your blood sugar as you have been told by your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Talk with your doctor before you drink alcohol or take products that have alcohol in them.
- Do not share your insulin product with another person. This includes any pens, cartridge devices, needles, or syringes, even if the needle has been changed. Sharing may pass

infections from one person to another. This includes infections you may not know you have.

- Use with care in children. Talk with the doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of low potassium levels like muscle pain or weakness, muscle cramps, or a heartbeat that does not feel normal.
- Blurred eyesight.
- Fever or chills.
- Very bad dizziness or passing out.
- Mood changes.
- Seizures.
- Slurred speech.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Thick skin, pits, or lumps where the injection was given.
- Low blood sugar may occur. Signs may be dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating. Call the doctor right away if any of these signs occur. Follow what you have been told to do if low blood sugar occurs. This may include taking glucose tablets, liquid glucose, or some fruit juices.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Irritation where the shot is given.
- Weight gain.
- Signs of a common cold.
- Throat irritation.
- Flu-like signs.
- Headache.
- Stomach pain.
- Back pain.
- Upset stomach or throwing up.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- It is given as a shot into the fatty part of the skin on the top of the thigh, belly area, or upper arm.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- If you use this drug once a day, use with the evening meal or at bedtime.
- If you use this drug twice a day, use the evening dose with the evening meal, at bedtime, or 12 hours after the morning dose.
- Move site where you give the shot each time.
- Do not give into skin that is thickened, or has pits or lumps.
- Do not give into skin that is irritated, tender, bruised, red, scaly, hard, scarred, or has stretch marks.
- Do not use if the solution is cloudy, leaking, or has particles.

- Do not use if solution changes color.
- Do not shake.
- Do not mix this insulin in the same syringe with other types of insulin.
- Do not mix this drug with other drugs in the same syringe.
- If needed, you may inject this drug and other drugs in the same area of the body, but not right next to each other.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.
- This drug must not be used in an insulin pump. If you have questions, talk with the doctor.

<u>Vials:</u>

• Do not draw into a syringe and store for future use.

Cartridges and prefilled pens:

- Remove all pen needle covers before injecting a dose (there may be 2). If you are not sure what type of pen needle you have or how to use it, talk with the doctor.
- This product may make a clicking sound as you prepare the dose. Do not prepare the dose by counting the clicks. Doing so could lead to using the wrong dose.
- Take off the needle after each shot. Do not store this device with the needle on it.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next shot, skip the missed shot and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store unopened containers in a refrigerator. Do not freeze.
- Do not use if it has been frozen.
- If an unopened container has been stored at room temperature, be sure you know how long you can leave this drug at room temperature before you need to throw it away. If you are not sure, talk with the doctor or pharmacist.

- Protect from heat and light.
- After opening, be sure you know how long the product is good for and how to store it. Ask the doctor or pharmacist if you are not sure.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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