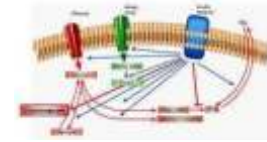


# R<sub>x</sub> RECOMBINANT HUMAN INSULIN

(Insulin is required by the cells of the body in order for them to remove and use glucose from the blood)



## GENERIC NAME: insulin

### DRUG CLASS AND MECHANISM

**Insulin** is a naturally-occurring hormone secreted by the pancreas. Insulin is required by the cells of the body in order for them to remove and use glucose from the blood. From glucose the cells produce the energy that they need to carry out their functions. Researchers first gave an active extract of the pancreas containing insulin to a young diabetic patient in 1922, and the FDA first approved insulin in 1939. Currently, insulin used for treatment is derived from beef and pork pancreas as well as recombinant (human) technology. The first recombinant human insulin was approved by the FDA in 1982. Patients with diabetes mellitus have an inability to take up and use glucose from the blood, and, as a result, the glucose level in the blood rises. In type 1 diabetes, the pancreas cannot produce enough insulin. Therefore, insulin therapy is needed. In type 2 diabetes, patients produce insulin, but cells throughout the body do not respond normally to the insulin. Nevertheless, **insulin** also may be used in type 2 diabetes to overcome the resistance of the cells to insulin. By increasing the uptake of glucose by cells and reducing the concentration of glucose in the blood, insulin prevents or reduces the long-term complications of diabetes, including damage to the blood vessels, eyes, kidneys, and nerves. Insulin is administered by injection under the skin (subcutaneously). The subcutaneous tissue of the abdomen is preferred because absorption of the insulin is more consistent from this location than subcutaneous tissues in other locations.

Regular (rapid onset of action, short duration of action) and NPH (slower onset of action, longer duration of action) human insulin are the most commonly-used preparations. Regular insulin has an onset of action (begins to reduce blood sugar) within 30 minutes of injection, reaches a peak effect at 1-3 hours, and has effects that last 6-8 hours.

**NPH** insulin is an insulin with an intermediate duration of action. It has an onset of action starting about 2 hours following injection. It has a peak effect 4-12 hours after injection, and a duration of action of 18-26 hours.

Lente insulin also is an insulin with an intermediate duration of action. It has an onset of action 2-4 hours after injection, a peak activity 6-12 hours after injection, and a duration of action of 18 to 26 hours. Ultralente insulin is a long-acting insulin with an onset of action 4-8 hours after injection, a peak effect 10-30 hours after injection, and a duration of action of more than 36 hours.

An ultra rapid-acting insulin, insulin lispro is a chemically-modified, natural insulin. It was approved by the FDA in June, 1996. As compared to regular insulin, insulin lispro has a more rapid onset of action, an earlier peak effect, and a shorter duration of action. It reaches peak activity 0.5-2.5 hours after injection. Therefore, insulin lispro should be injected 15 minutes before a meal as compared to regular insulin which is injected 30-60 minutes before a meal.

Insulin aspart and insulin glargine are both human insulin that have had their chemical composition slightly altered. The chemical changes provide insulin aspart with a faster onset of action (20 minutes) and a shorter duration of action (3-5 hours) than regular human insulin. It reaches peak activity 1-3 hours after injection. Insulin glargine has a slower onset of action (70 minutes) and a longer duration of action (24 hours) than regular human insulin. Its activity does not peak.

**GENERIC:** no

**PRESCRIPTION:** yes

### PREPARATIONS

Insulin comes in three different forms-vials, prefilled syringes, and cartridges. The cartridges are to be used in a pen-like device that simplifies injection. Human recombinant insulin, insulin lispro, insulin aspart, and insulin glargine are the commonly-used insulins. Beef and pork insulin are infrequently used. Regular human insulin (Novolin R, Humulin R) is available in vials, cartridges, and prefilled syringes. NPH human insulin (Novolin N, Humulin N) is available in vials, cartridges and prefilled syringes. A mixture of 70% NPH human insulin and 30% regular human insulin (Novolin 70/30, Humulin 70/30) is available in vials, cartridges and pre-filled syringes.

A mixture of 50% **NPH** human insulin and 50% regular human insulin (Humulin 50/50) is available in vials.

Lente human insulin (Novolin L, Humulin L) is available in vials. Ultralente human insulin (Humulin U) is available in vials.

Insulin lispro (Humalog) is available in vials and cartridges. Insulin aspart (Novolog) is available in vials and cartridges.

Insulin glargine (Lantus) is available in vials and cartridges.

### PRESCRIBED FOR

Insulin is prescribed for the treatment of type 1 and type 2 diabetes mellitus.

**DOSING:** The abdomen is the preferred site for insulin injection, but the sites of injection must be rotated in order to prevent erosion of the fat beneath the skin, a condition called lipodystrophy.

### DRUG INTERACTIONS

Several drugs augment the action of insulin and may lower blood glucose to a dangerous level (hypoglycemia). To prevent hypoglycemia when these drugs are used, the dose of insulin may need to be reduced. Such drugs include alcohol, MAO inhibitors like phenelzine (Nardil), beta-blockers like propranolol (Inderal), salicylates like aspirin (Bayer) or salsalate (Disalcid), and anabolic steroids like methyltestosterone (Android).

There are other drugs that augment the blood glucose-lowering effect of insulin, but they are less likely to interact with insulin or have less of an effect. Such drugs include tetracycline antibiotics like doxycycline (Vibramycin), guanethidine (Ismelin), oral hypoglycemic drugs like glyburide (Diabeta), sulfa antibiotics like sulfadiazine, and ACE inhibitors like captopril (Capoten).

There also are drugs that decrease the effect of insulin. Interactions are less likely and/or less serious. These drugs include diltiazem (Cardizem), niacin, corticosteroids like prednisone, estrogens, oral contraceptives, thyroid hormones like levothyroxine (Synthroid), isoniazid, epinephrine, thiazide diuretics like hydrochlorothiazide, and furosemide (Lasix).

### USES

Insulin is used to treat diabetes mellitus. Controlling high blood sugar helps prevent heart disease, strokes, kidney disease, circulation problems, and blindness.

### HOW TO USE

Insulin must be injected. Learn the proper way to inject insulin. Check the dose carefully. Clean the injection site with rubbing alcohol. Change the injection site daily to prevent skin bulges or pockets. Do not inject cold insulin. The insulin container you are currently using can be kept at room temperature. The length of time you can store it at room temp. depends on the product. Consult your pharmacist. Insulin is frequently injected 30 minutes before a meal. Some inject at bedtime. Ask your pharmacist or nurse for details of injecting insulin as it varies depending on your insulin treatment plan. Monitor your urine or blood sugar as prescribed. Keep track of your results. This is very important in order to determine the correct insulin dose. Follow all of your doctor's directions carefully.

### SIDE EFFECTS

Insulin may cause minor and usually temporary side effects such as rash, irritation or redness at the injection site. To help prevent hypoglycemia, eat meals on a regular schedule. Too much insulin can cause low blood sugar (hypoglycemia). The symptoms include cold sweat, shaking, rapid heart rate, weakness, headache and fainting which, if untreated, may lead to slurred speech and other behaviors that resemble drunkenness. If you experience these symptoms, eat a quick source of sugar such as glucose (glucose, etc.) table sugar, orange juice, honey or non-diet soda. Tell your doctor about the reaction. Too little insulin can cause symptoms of high blood sugar (hyperglycemia) which include confusion, drowsiness, rapid breathing, fruity breath odor, increased urination or unusual thirst. If these symptoms occur, contact your doctor. Your insulin dose needs adjustment. In the unlikely event you have an allergic reaction to this drug, seek medical attention immediately. 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

Tell your doctor if you have had allergic reactions, especially to beef, pork or human insulin and of your medical history especially of: thyroid problems, kidney or liver disease, any current infection. Dosage adjustments may be required when you become ill, are under stress, or when quitting smoking. Consult your doctor if you catch a cold or the flu, become nauseated or if your blood glucose levels are high. Fat deposits can occur if injection site is not rotated. Check your sugar readings before and after exercise. You may need a

snack beforehand. Tell your doctor if you are pregnant before using this drug. Insulin is not excreted into breast milk. Nevertheless, consult your doctor before breast-feeding.

#### DRUG INTERACTIONS

Before you use insulin, tell your doctor of all prescription and nonprescription drugs you are taking especially: beta-blockers (acebutolol, atenolol, betaxolol, esmolol, metoprolol, carteolol, nadolol, penbutolol, pindolol, propranolol, timolol, bisoprolol), fenfluramine, MAO inhibitors (e.g., furazolidone, linezolid, phenelzine, selegiline, tranylcypromine), salicylates (aspirin-like compounds), dexfenfluramine, steroids (e.g., prednisone, hydrocortisone), birth control pills,

sulfa antibiotics, water pills, ACE inhibitors, octreotide, isoniazid, niacin, estrogens, cold and allergy drugs, drugs that contain alcohol or sugar. Other medications can affect the action of insulin and can alter the results of urine tests for sugar or ketones. Do not start or stop any medicine without doctor or pharmacist approval.

#### 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 unconsciousness, seizures, muscle weakness, slow or shallow breathing, headache, vomiting, fever, diarrhea, shakiness, nervousness, fast heartbeat, hunger, or sweating.

#### 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

Insulin may be stored under refrigeration up to the expiration date noted on the package and must be discarded after that date. Consult your pharmacist for the storage requirements of your particular form/type of insulin, including room temperature storage options. Do not expose insulin to heat or sunlight. Do not freeze.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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Revised November 2010