

PRONUNCIATION: (IN-sue-lin GLUE-lih-seen)

COMMON BRAND NAME(S): Apidra

HOW TO USE: Read the Patient Information Leaflet provided by your pharmacist before you start using insulin glulisine and each time you get a refill. If you have any questions regarding the information, consult your doctor or pharmacist. Learn all preparation and usage instructions, including how to inject this medication properly and how to self-manage your diabetes (e.g., monitoring blood glucose, recognizing and treating high/low blood sugar). For additional information, consult your doctor, diabetic educator, or pharmacist. Before using, inspect this product visually for particles or discoloration. If either is present, do not use the insulin. Before injecting each dose, clean the injection site with rubbing alcohol. It is important to change the location of the injection site daily to avoid developing problem areas under the skin (lipodystrophy). Insulin glulisine may be injected in the abdominal wall, the thigh, or the back of the upper arm. Inject this medication under the skin within 15 minutes before eating a meal or within 20 minutes after starting the meal as directed by your doctor. Because this insulin is fast-acting, not eating immediately after giving a dose of this insulin may lead to low blood sugar (hypoglycemia). 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 in order to get the most benefit from it. To help you remember, use it at the same time(s) each day. Do not inject this medication into a muscle. Also, insulin glulisine must not be given into a vein unless you are in the hospital where you can be closely monitored because severely low blood sugar may result. If you are directed to inject this insulin with an infusion pump, read the instruction manual and directions that come with the infusion pump. If you have any questions regarding the information, consult your doctor, diabetic educator, or pharmacist. Avoid exposing the pump or its tubing to direct sunlight or other heat sources. This product may be mixed only with certain other insulin products such as NPH insulin. Consult your pharmacist about which products may be mixed and the proper method for mixing insulin. Never inject a mixture of different insulins into a vein. Do not mix insulins if you are using an insulin pump. Do not change brands or types of insulin without directions on how to do so from your doctor. Learn how to store and discard needles and medical supplies safely. Consult your pharmacist.

USES: Insulin glulisine is a man-made product almost identical to human insulin. It is used to treat diabetes mellitus. Like other insulin products, it works by helping sugar (glucose) get into cells. It starts working faster and lasts for a shorter time than regular insulin. Insulin glulisine is usually used in combination with a medium- or long-acting insulin product to control high blood sugar. 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.

SIDE EFFECTS: Injection site reactions (e.g., pain, redness, irritation) 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. Tell your doctor immediately if this unlikely but serious side effect occurs: muscle pain. This medication can cause low blood sugar (hypoglycemia). This effect may occur if you do not consume enough calories (from food, juices, fruit, etc.) or you have used too much insulin glulisine. The symptoms include chills, cold sweat, blurred vision, dizziness, drowsiness, shaking, rapid heart rate, weakness, headache, fainting, tingling of the hands or feet, or hunger. It is a good habit to carry glucose tablets or gel to treat low blood sugar. If you are in a situation where you don't have these reliable forms of glucose, eat a quick source of sugar such as table sugar, honey, or candy, or drink a glass of orange juice or non-diet soda to quickly raise your blood sugar level. 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 glulisine can cause symptoms of high blood sugar (hyperglycemia). Symptoms include thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, or fruity breath odor. If these symptoms occur, tell your doctor immediately. Your dosage may need to be increased. 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, fast heartbeat, sweating, 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 glulisine, tell your doctor or pharmacist if you are allergic to it; or to other insulins; or if you have any other allergies. This product may contain inactive ingredients (such as cresol), 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: kidney disease, liver disease, 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 using this medication because it can increase the risk of developing hypoglycemia. 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. 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 hypoglycemia. Children may be more sensitive to the effects of this drug, especially hypoglycemia. 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 whether this drug passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. 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 of: other insulin products (e.g., regular, NPH), oral diabetes medicine (e.g., glyburide, pioglitazone), ACE inhibitors (e.g., enalapril, lisinopril), clonidine, corticosteroids (e.g., prednisone), danazol, disopyramide, estrogens and progestins (including birth control pills), fibrates (e.g., clofibrate, gemfibrozil), fluoxetine, guanethidine, isoniazid, lithium, MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine), niacin, pentamidine, pentoxifylline, propoxyphene, protease inhibitors (e.g., indinavir, ritonavir), anti-psychotic drugs (e.g., phenothiazines such as chlorpromazine or atypical anti-psychotics such as clozapine, olanzapine), quinolone antibiotics (e.g., ciprofloxacin), reserpine, salicylates (e.g., aspirin), somatropin, sulfa antibiotics (e.g., sulfamethoxazole), sympathomimetic drugs (e.g., albuterol, epinephrine), thyroid medicine, "water pills" (diuretics such as furosemide, hydrochlorothiazide). 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: shakiness, rapid heartbeat, unexplained sweating, loss of consciousness.

NOTES: Do not share this medication 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. Check your blood sugar levels regularly as directed by your doctor or pharmacist. 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: It is best to refrigerate the unopened vial/cartridge/pen between 36-46 degrees F (2-8 degrees C). Do not freeze. Discard the insulin if it has been frozen. Unopened insulin may also be stored at room temperature below 77 degrees F (25 degrees C), but in that case it must be discarded after 28 days. Opened vials may be stored in the refrigerator or at room temperature. Opened cartridges with the delivery device attached should not be refrigerated but should be kept at room temperature. Do not store the delivery device in the refrigerator. Opened pens should not be refrigerated but should be kept at room temperature. When stored at room temperature, opened containers should be kept below 77 degrees F (25 degrees C), away from direct heat and light. Discard all opened containers of insulin glulisine 28 days after opening. If using this drug in an insulin pump, do not store this drug in the pump for more than 48 hours. Doing so may lead to ineffective therapy and high blood sugars. Do not expose the insulin in your pump to direct sunlight or temperatures above 98.6 degrees F (37 degrees C). Keep all medicines away from children and pets. 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.