

PRONUNCIATION: (ex-EN-a-tide)

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

**HOW TO USE:** Read the Medication Guide and the Pen User Manual provided by your pharmacist before you start using exenatide and each time you get a refill. If you have questions regarding the information, consult your doctor or pharmacist. Exenatide is injected under the skin (subcutaneous-SC) in the thigh, abdomen, or upper arm usually twice daily within the hour before the morning and evening meals (or before the two main meals of the day, approximately 6 hours or more apart). Exenatide should not be injected after a meal since it will be much less effective at that time. Antibiotics and birth control pills should be taken at least 1 hour before exenatide, since exenatide may decrease their effectiveness if used at the same time. If the antibiotic or birth control pill needs to be taken with food then take it with a meal or snack when exenatide is not injected (such as lunch). (See also Drug Interactions section) Make sure you learn the technique and procedures for preparing the drug and for self-injection. Consult your doctor or pharmacist if you have any questions. 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 problem areas under the skin. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. The dosage is based on your medical condition and your response to therapy. Use this medication regularly in order to get the most benefit from it. Learn how to store and discard needles and medical supplies safely. Consult your pharmacist. Tell your doctor if your condition persists or worsens (blood sugar levels are too high or low).

**USES:** Exenatide is used along with other oral diabetes medications (e.g., metformin, chlorpropamide, glipizide, glyburide) and a proper diet and exercise program to control high blood sugar in people with Type 2 diabetes (non-insulin dependent 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. Exenatide acts like the natural blood sugar-lowering hormone called incretin. It works in several ways, especially by stimulating the release of the body's natural insulin in response to high sugar levels after a meal, thereby lowering your blood sugar. Exenatide is not a substitute for insulin if you require insulin treatment. This medication should not be used in patients with Type 1 diabetes or for the treatment of extremely high blood sugars (diabetic ketoacidosis).

**SIDE EFFECTS:** Nausea, vomiting, diarrhea, nervousness or upset stomach may occur as your body adjusts to the medication. Nausea usually lessens as you continue to use exenatide. Other side effects include decreased appetite/food intake or decreased body weight. If any of these effects persist or worsen, contact 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. Rare but serious pancreas problems (pancreatitis) can occur while using exenatide. Get immediate medical attention if you develop severe/persistent stomach/abdominal pain, or persistent severe nausea/vomiting. Do not restart exenatide treatment without first talking with your doctor. Tell your doctor immediately if this rare but serious side effect occurs: a change in the amount of your urine. 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 exenatide, tell your doctor or pharmacist if you are allergic to it; 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. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, severe stomach/intestinal disorders (e.g., digestion problems such as gastroparesis, or pancreatitis). You may experience blurred vision, headache, 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 alcoholic beverages since alcohol can affect your blood sugar. Symptoms of high blood sugar (hyperglycemia) include thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, or fruity breath odor. If these symptoms occur, tell your doctor immediately. Your medication dosage may need to be increased. During times of severe stress, such as fever, infection, injury or surgery, it may be more difficult to control your blood sugar. Consult your doctor, as a change in your medication or how often you test your blood sugar may be required. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. Your doctor may substitute insulin for this drug during your pregnancy. Follow all instructions carefully. It is unknown if this medication passes into breast milk, but it is unlikely to harm a nursing infant. 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 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: anti-diabetic drugs (e.g., sulfonylureas such as glipizide, glyburide, chlorpropamide), birth control pills (see also How To Use section), oral antibiotics, warfarin. 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. While exenatide does not cause low blood sugar (hypoglycemia) itself, it may increase the risk of low blood sugar when used in combination with certain other diabetes medications (pioglitazone, rosiglitazone, sulfonylureas such as chlorpropamide, glipizide, glyburide). Be sure you are aware of the signs of low blood sugar and how to prevent and treat it (see your other diabetes medication leaflet for more details). Talk with you doctor or pharmacist about whether your dose of sulfonylurea needs to be lowered or not. 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 severe nausea, severe vomiting and rapidly dropping blood sugar levels (hypoglycemia), resulting in confusion, fainting, sweating, fast heartbeat.

**NOTES:** Do not share this medication, the pens or the needles with others. You should attend a diabetes education program to understand diabetes, its complications, 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., kidney function tests, fasting blood glucose, hemoglobin A1c) 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.

**MISSED DOSE:** If a dose is missed, skip the missed dose and resume your usual dosing schedule with the next scheduled dose. Do not double the dose to catch up.

**STORAGE:** Before using the exenatide pen for the first time, store it in the refrigerator at 36-46 degrees F (2-8 degrees C). Do not freeze. After first use, exenatide can be stored at room temperature at or below 77 degrees F (25 degrees C). Protect from light at all times. Discard 30 days after first use, even if some drug remains in the pen. 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.