

Medication Guide

Exenatide (ex en' a tide) Injection, USP for subcutaneous use

Read this Medication Guide and the Instructions for Use that comes with exenatide injection before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have questions about exenatide injection after reading this information, ask your healthcare provider or pharmacist.

What is the most important information I should know about exenatide injection?

- **Do not share your exenatide injection pen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.**
- **Serious side effects can happen in people who take exenatide injection, including inflammation of the pancreas (pancreatitis) which may be severe and lead to death.** Stop using exenatide injection and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back. These may be symptoms of pancreatitis.

What is exenatide injection?

- Exenatide is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus, when used with a diet and exercise program.
- Exenatide is not insulin.
- Exenatide injection is not a substitute for insulin.
- The use of exenatide injection with short acting insulin is not recommended.
- The use of exenatide injection with rapid acting insulin is not recommended.
- Exenatide injection is not for people with type 1 diabetes or people with diabetic ketoacidosis.
- It is not known if exenatide injection can be used in people who have had pancreatitis.
- It is not known if exenatide injection is safe and effective in children.
- Exenatide injection should not be used in people who have severe kidney problems.

Who should not use exenatide injection?

Do not use exenatide injection if:

- you have had a severe allergic reaction to exenatide or any of the other ingredients in exenatide injection. See the end of this Medication Guide for a complete list of ingredients in exenatide injection.

Symptoms of a severe allergic reaction with exenatide injection may include:

- swelling of your face, lips, tongue, or throat
 - problems breathing or swallowing
 - severe rash or itching
 - fainting or feeling dizzy
 - very rapid heartbeat
- you have a history of low blood platelet count from using exenatide medicines (drug-induced thrombocytopenia).

Before taking exenatide injection, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had problems with your pancreas.
- have severe problems with your stomach, such as delayed emptying of your stomach (gastroparesis) or problems with digesting food.
- have or have had kidney problems, or have had a kidney transplant.
- are scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation).
- are pregnant or plan to become pregnant. It is not known if exenatide injection will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking exenatide injection. Talk to your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if exenatide passes into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while taking exenatide injection.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Exenatide injection may affect the way some medicines work and some other medicines may affect the way exenatide injection works.

Especially tell your healthcare provider if you take:

- other anti-diabetes medicines, especially sulfonylurea medicines or insulin.
- birth control pills that are taken by mouth (oral contraceptives). Exenatide injection may lower the amount of the medicine in your blood from your birth control pills and they may not work as well to prevent pregnancy. Take your birth control pills at least one hour before your injection of exenatide. If you must take your birth control pills with food, take it with a meal or snack at a time when you do not also take exenatide injection.
- an antibiotic. Take antibiotic medicines at least one hour before taking exenatide injection. If you must take your antibiotic with food, take it with a meal or snack at a time when you do not also take exenatide injection.
- warfarin sodium (Coumadin[®], Jantoven[®]).
- a blood pressure medicine.
- a water pill (diuretic).
- a pain medicine.
- lovastatin (Altoprev[®], Mevacor[®], Advicor[®]).

How should I take exenatide injection?

See the Instructions for Use that comes with exenatide injection for instructions for using the exenatide injection pen and injecting exenatide.

- Your healthcare provider may prescribe exenatide injection alone or with certain other medicines to help control your blood sugar.
- Use exenatide injection exactly as your healthcare provider tells you to.
- **Your healthcare provider should teach you how to inject exenatide before you use it for the first time.**
- Inject your dose of exenatide under the skin (subcutaneous injection) of your upper leg (thigh), stomach area (abdomen), or upper arm as instructed by your healthcare provider. Do not inject into a vein or muscle.
- **Do not** mix exenatide injection and insulin in the same syringe or vial even if you take them at the same time.
- Exenatide is injected two times each day, at any time within 60 minutes (1 hour) **before** your morning and evening meals (or **before** the two main meals of the day, approximately 6 hours or more apart). **Do not take exenatide injection after your meal.**

- If you miss a dose of exenatide injection, skip that dose and take your next dose at the next prescribed time. Do not take an extra dose or increase the amount of your next dose to make up for a missed dose.
- If you use too much exenatide, call your healthcare provider. Too much exenatide injection can cause your blood sugar to drop quickly and you may have symptoms of low blood sugar. You may need medical treatment right away. Too much exenatide injection can also cause severe nausea and vomiting.
- If you see your blood sugar increasing during treatment with exenatide injection, talk to your healthcare provider because you may need to adjust your current treatment plan for your diabetes.

What are the possible side effects of exenatide injection?

Exenatide injection may cause serious side effects, including:

- See “**What is the most important information I should know about exenatide injection?**”
- **Low blood sugar (hypoglycemia).** Your risk for getting low blood sugar is higher if you take exenatide injection with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be lowered while you use exenatide injection. Signs and symptoms of low blood sugar may include:
 - headache
 - drowsiness
 - weakness
 - hunger
 - fast heart beat
 - dizziness
 - confusion
 - anxiety, irritability or mood change
 - sweating
 - feeling jittery
 - blurred vision
 - slurred speech

Talk with your healthcare provider about how to treat low blood sugar.

- **Kidney problems.** Exenatide injection may cause new or worse problems with kidney function, including kidney failure. Dialysis or kidney transplant may be needed.
 - **While taking exenatide injection:** Call your healthcare provider right away if you have nausea, vomiting, or diarrhea that will not go away, or if you cannot take liquids by mouth. You may be at increased risk for kidney problems.
- **Stomach problems.** Other medicines like exenatide injection may cause severe stomach problems. It is not known if exenatide injection causes stomach problems or will cause your stomach problems to worsen.
- **Low blood platelet count (drug-induced thrombocytopenia).** Exenatide injection may cause the number of platelets in your blood to be reduced. When your platelet count is too low, your body cannot form blood clots. You could have serious bleeding that could lead to death. **Stop using exenatide injection and call your healthcare provider right away if you have unusual bleeding or bruising.**
- **Severe allergic reactions.** Severe allergic reactions can happen with exenatide injection. Stop taking exenatide injection, and get medical help right away if you have any symptom of a severe allergic reaction. See “**Who should not use exenatide injection?**”
- **Gallbladder problems.** Gallbladder problems have happened in some people who take exenatide injection. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include:
 - pain in your upper stomach (abdomen)
 - fever
 - yellowing of skin or eyes (jaundice)
 - clay-colored stools
- **Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation).** Exenatide injection may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking exenatide injection before you are scheduled to have surgery or other procedures.

The most common side effects of exenatide injection include:

- nausea
- vomiting
- diarrhea
- feeling jittery
- dizziness
- headache
- indigestion
- constipation
- weakness

Nausea is most common when you first start using exenatide injection but may decrease over time.

Talk to your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of exenatide injection.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store exenatide injection?

- Store your new, unused exenatide injection pen in the original carton in a refrigerator at 36° to 46°F (2° to 8°C).
- After first use, keep your exenatide injection pen at a temperature cooler than 77°F (25°C).
- Do not freeze your exenatide injection pen. Do not use exenatide injection if it has been frozen.
- Protect exenatide injection from light.
- Use an exenatide injection pen for only 30 days. Throw away a used exenatide injection pen after 30 days, even if there is some medicine left in the pen.
- Do not use exenatide injection after the expiration date printed on the label.
- **Keep your exenatide injection pen, pen needles and all medicines out of the reach of children.**

General information about the safe and effective use of exenatide injection.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use exenatide injection for a condition for which it was not prescribed. Do not give exenatide injection to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about exenatide injection that is written for health professionals.

What are the ingredients in exenatide injection?

Active ingredient: exenatide, USP

Inactive ingredients: metacresol, mannitol, glacial acetic acid and sodium acetate trihydrate in water for injection.

For more information, go to www.amneal.com or call 1-877-835-5472.

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