

**Medication Guide**  
**BYDUREON™ (by-DUR-ee-on)**  
**(exenatide extended-release**  
**for injectable suspension)**

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

**What is the most important information I should know about BYDUREON?**

**Serious side effects may happen in people who take BYDUREON, including:**

- 1. Possible thyroid tumors, including cancer.** During the drug testing process, the medicine in BYDUREON caused rats to develop tumors of the thyroid gland. Some of these tumors were cancers. It is not known if BYDUREON will cause thyroid tumors or a type of thyroid cancer called medullary thyroid cancer in people.
  - Before you start taking BYDUREON, tell your healthcare provider if you or any of your family members have had thyroid cancer, especially medullary thyroid cancer, or Multiple Endocrine Neoplasia syndrome type 2. **Do not** take BYDUREON if you or any of your family members have medullary thyroid cancer, or if you have Multiple Endocrine Neoplasia syndrome type 2. People with these conditions already have a higher chance of developing medullary thyroid cancer in general and should not take BYDUREON.
  - While taking BYDUREON, tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer.
- 2. Inflammation of the pancreas (pancreatitis),** which may be severe and lead to death.

**Before taking BYDUREON, tell your healthcare provider if you have had:**

- pancreatitis
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

These medical conditions can make you more likely to get pancreatitis. It is not known if having these conditions will lead to a higher chance of getting pancreatitis while taking BYDUREON.

**Stop taking BYDUREON and call your healthcare provider right away if** you have pain in your stomach area (abdomen) that is severe, and will not go

away. The pain may happen with or without vomiting. The pain may be felt going from your abdomen through to your back. This type of pain may be a symptom of pancreatitis.

### **What is BYDUREON?**

- BYDUREON is an injectable prescription medicine that may improve blood sugar (glucose) in adults with type 2 diabetes mellitus, and should be used along with diet and exercise.
- BYDUREON is a long-acting form of the medication contained in BYETTA. Do not use BYDUREON and BYETTA together.
- BYDUREON is not recommended as the first choice of medication for treating diabetes.
- BYDUREON is not insulin.
- It is not known if BYDUREON is safe and effective when used with insulin.
- BYDUREON is not for use in people with type 1 diabetes or people with a condition caused by very high blood sugar (diabetic ketoacidosis).
- It is not known if BYDUREON is safe and effective in children. BYDUREON is not recommended for use in children.
- It is not known if BYDUREON is safe and effective in people who have a history of pancreatitis.
- BYDUREON has not been studied in people who have severe kidney problems.

### **Who should not use BYDUREON?**

#### **Do not use BYDUREON if:**

- you or any of your family members have a history of medullary thyroid cancer.
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). This is a disease where people have tumors in more than one gland in their body.
- you are allergic to exenatide or any of the ingredients in BYDUREON. See the end of this Medication Guide for a complete list of ingredients in BYDUREON. Symptoms of a severe allergic reaction may include:
  - swelling of your face, lips, tongue, or throat
  - fainting or feeling dizzy
  - problems breathing or swallowing
  - very rapid heartbeat
  - severe rash or itching

Talk to your healthcare provider before taking this medicine if you have any of these conditions.

## **What should I tell my healthcare provider before using BYDUREON?**

### **Before using BYDUREON, tell your healthcare provider if you:**

- have any of the conditions listed in the section “What is the most important information I should know about BYDUREON?”
- have severe problems with your stomach such as slow emptying of your stomach (gastroparesis) or problems digesting food.
- have or have had kidney problems, or have had a kidney transplant.
- have any other medical conditions.
- are pregnant or are planning to become pregnant. It is not known if BYDUREON may harm your unborn baby. Tell your healthcare provider if you become pregnant while taking BYDUREON.
- **Pregnancy Registry:** Amylin Pharmaceuticals, Inc. has a registry for women who take BYDUREON during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you take BYDUREON at any time during pregnancy, you may enroll in this registry by calling 1-800-633-9081.
- are breastfeeding or plan to breastfeed. It is not known if BYDUREON passes into your breast milk. You and your healthcare provider should decide if you will take BYDUREON or breastfeed. You should not do both without talking with your healthcare provider first.

**Tell your healthcare provider about all of the medicines you take**, including prescription and nonprescription medicines, vitamins, and herbal supplements. BYDUREON may affect the way some medicines work and some other medicines may affect the way BYDUREON works.

Especially tell your healthcare provider if you take:

- other diabetes medicines, especially insulin or a sulfonylurea
- any medicine taken by mouth
- warfarin sodium (Coumadin<sup>®</sup>, Jantoven<sup>®</sup>)

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

## **How should I use BYDUREON?**

**For detailed instructions, see the Instructions for Use that comes with your BYDUREON.**

- Use BYDUREON exactly as your healthcare provider tells you to.
- BYDUREON is injected once every seven days (weekly) any time during the day.

- BYDUREON is a subcutaneous injection. Inject BYDUREON into your skin exactly the way your healthcare provider told you to. You can take the injection in your stomach area (abdomen), your thigh, or the back of your upper arm. Each week you can use the same area of your body. But be sure to choose a different injection site in that area.
- You can take BYDUREON with or without food.
- **If you miss a dose of BYDUREON, it should be taken as soon as you remember, provided the next regularly scheduled dose is due at least three days later.**
- **If you miss a dose of BYDUREON and the next regularly scheduled dose is due one or two days later, do not take the missed dose but take BYDUREON on the next regularly scheduled day.**
- **Do not** take 2 doses of BYDUREON less than 3 days apart.
- If you want to change your dosing day, you can. Your new dosing day must be at least 3 days after your last dose.
- Your healthcare provider must teach you how to inject BYDUREON before you use it for the first time. If you have any questions or do not understand the instructions, talk with your healthcare provider or pharmacist.
- BYDUREON must be injected right after you mix it.
- **If you are taking BYETTA and your healthcare provider prescribed BYDUREON, you should follow your healthcare provider's instructions about when to stop taking BYETTA and when to start taking BYDUREON.** BYETTA is a different form of the same medicine that is in BYDUREON, so do not take BYETTA when you are taking BYDUREON. When you first change from BYETTA to BYDUREON, your blood sugar levels may be higher than usual and should get better in about 2 weeks.
- Inject your dose of BYDUREON under the skin (subcutaneous injection), as you are told to by your healthcare provider. **Do not inject BYDUREON into a vein or muscle.**
- **Do not** share your BYDUREON tray with another person even if the needle is changed. Sharing your tray with another person can cause you or someone else to get an infection.
- Follow your healthcare provider's instructions for diet, exercise, how often to test your blood sugar, and when to get your HbA<sub>1c</sub> checked. If you see your blood sugar increasing during treatment with BYDUREON, talk to your healthcare provider because you may need to adjust your current treatment plan for your diabetes.

- Talk to your healthcare provider about how to manage high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia), and how to recognize problems that can happen with your diabetes.

### **What are the possible side effects of BYDUREON?**

**BYDUREON can cause serious side effects, including:**

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

Talk with your healthcare provider about how to recognize and treat low blood sugar. Make sure that your family and other people around you a lot know how to recognize and treat low blood sugar.

- **Kidney problems (kidney failure).** BYDUREON may cause nausea, vomiting or diarrhea leading to loss of fluids (dehydration). Dehydration may cause kidney failure, which can lead to the need for dialysis. This can happen in people who have never had kidney problems before. Drinking plenty of fluids may reduce your chance of dehydration. Call your healthcare provider right away if you have nausea, vomiting, or diarrhea that will not go away, or if you cannot drink liquids by mouth.
- **Severe allergic reactions.** Severe allergic reactions can happen with BYDUREON. Stop taking BYDUREON, and get medical help right away if you have any symptom of a severe allergic reaction. **See “Who should not take BYDUREON?”**

The most common side effects of BYDUREON include:

- nausea
- diarrhea
- headache
- vomiting
- constipation

- itching at the injection site
- a small bump (nodule) at the injection site
- indigestion

Nausea is most common when you first start using BYDUREON, but decreases over time in most people as their body gets used to the medicine.

Talk to your healthcare provider about any side effect that bothers you or does not go away.

These are not all the side effects of BYDUREON. For more information, ask your healthcare provider or pharmacist.

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 BYDUREON?**

- Store BYDUREON in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not use BYDUREON past the expiration date. The expiration date is labeled *EXP* and can be found on the paper cover of the single-dose tray.
- Do not freeze BYDUREON trays. Do not use BYDUREON if it has been frozen.
- Protect BYDUREON from light until you are ready to prepare and use your dose.
- If needed, you can keep your BYDUREON tray out of the refrigerator at 68°F to 77°F (20°C to 25°C) for up to 4 weeks.
- See the Instructions for Use for information about how to throw away your used BYDUREON parts.

**Keep BYDUREON, and all medicines, out of the reach of children.**

### **General information about safe and effective use of BYDUREON**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BYDUREON for a condition for which it was not prescribed. Do not give your BYDUREON to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about BYDUREON. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about BYDUREON that is written for healthcare professionals.

For more information about BYDUREON, go to [www.BYDUREON.com](http://www.BYDUREON.com) or call 1-877-700-7365.

## **What are the ingredients in BYDUREON?**

### **Contents of vial:**

**Active ingredient:** exenatide

**Inactive ingredients:** polylactide-co-glycolide and sucrose.

### **Contents of liquid (diluent) in syringe:**

**Inactive ingredients:** carboxymethylcellulose sodium, polysorbate 20, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, sodium chloride, water for injection.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Manufactured by Amylin Pharmaceuticals, Inc., San Diego, CA 92121.

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