

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

Read this Medication Guide 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 to your healthcare provider about your medical condition or your treatment.

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

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

- **Possible thyroid tumors, including cancer.** 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. In studies with rats or mice, BYDUREON and medicines that work like BYDUREON caused thyroid tumors, including thyroid cancer. It is not known if BYDUREON will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use BYDUREON if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

**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 not recommended as the first choice of medicine for treating diabetes.
- BYDUREON is not a substitute for insulin and is not for use in people with type 1 diabetes or people with diabetic ketoacidosis.
- BYDUREON is a long-acting form of the medicine in BYETTA (exenatide). BYDUREON and BYETTA should not be used at the same time.
- It is not known if BYDUREON can be used in people who have had pancreatitis.
- It is not known if BYDUREON is safe and effective for use in children.

**Who should not use BYDUREON?**

**Do not use BYDUREON if:**

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- 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.

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

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

- have or have had problems with your pancreas, kidneys, or liver.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if BYDUREON will harm your unborn baby. Tell your healthcare provider if you become pregnant while using BYDUREON.
- are breastfeeding or plan to breastfeed. It is not known if BYDUREON passes into your breast milk. You should not use BYDUREON while breastfeeding without first talking with

your healthcare provider.

**Pregnancy Registry:** There is a registry for women who use BYDUREON during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you use BYDUREON at any time during pregnancy, you may enroll in this registry by calling 1-800-633-9081.

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

**Before using BYDUREON, talk to your healthcare provider about low blood sugar and how to manage it.** Tell your healthcare provider if you are taking other medicines to treat diabetes including insulin or sulfonylureas.

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

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

- Read the [Instructions for Use](#) that comes with BYDUREON.
- Use BYDUREON exactly as your healthcare provider tells you to.
- BYDUREON should be injected right away after you prepare your dose.
- **Your healthcare provider should show you how to use BYDUREON before you use it for the first time.**
- BYDUREON is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. **Do not** inject BYDUREON into a muscle (intramuscularly) or vein (intravenously).
- **Use BYDUREON 1 time each week on the same day each week at any time of the day.**
- BYDUREON may be taken with or without food.
- If you miss a dose of BYDUREON, take the missed dose as soon as possible if there are at least 3 days (72 hours) until your next scheduled dose. If there are less than 3 days remaining, skip the missed dose and take your next dose on the regularly scheduled day. **Do not** take 2 doses of BYDUREON within 3 days of each other.
- You may change the day of the week as long as your last dose was given 3 or more days before.
- **Do not** mix insulin and BYDUREON together in the same injection.
- You may give an injection of BYDUREON and insulin in the same body area (such as, your stomach area), but not right next to each other.
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.
- **Do not share your BYDUREON pen, prefilled syringe, or needles with another person.** You may give another person an infection or get an infection from them.
- **Your dose of BYDUREON and other diabetes medicines may need to change because of:** change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

## What are the possible side effects of BYDUREON?

BYDUREON may cause serious side effects, including:

- See "[What is the most important information I should know about BYDUREON?](#)"
- **inflammation of your pancreas (pancreatitis)**. Stop using BYDUREON 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.
- **low blood sugar (hypoglycemia)**. Your risk for getting low blood sugar may be higher if you use BYDUREON with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include:**
  - dizziness or light-headedness
  - sweating
  - confusion or drowsiness
  - headache
  - blurred vision
  - slurred speech
  - shakiness
  - fast heartbeat
  - anxiety, irritability, or mood changes
  - hunger
  - weakness
  - feeling jittery
- **kidney problems (kidney failure)**. In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.
- **stomach problems**. Other medicines like BYDUREON may cause severe stomach problems. It is not known if BYDUREON causes or worsens stomach problems.
- **serious allergic reactions**. Stop using BYDUREON, and get medical help right away if you have any symptoms of a serious allergic reaction, including itching, rash, or difficulty breathing.
- **injection-site reactions**. Serious injection-site reactions, with or without bumps (nodules), have happened in some people who use BYDUREON. Some of these injection-site reactions have required surgery. Call your healthcare provider if you have any symptoms of an injection-site reaction, including severe pain, swelling, blisters, an open wound, a dark scab.

**The most common side effects of BYDUREON may 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 possible 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.

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

**General information about the 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 pharmacist or healthcare provider for information about BYDUREON that is written for health 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 the powder:**

**Active Ingredient:** exenatide

**Inactive Ingredients:** polylactide-co-glycolide and sucrose

**Contents of liquid (diluent):**

**Inactive Ingredients:** carboxymethylcellulose sodium, polysorbate 20, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, sodium chloride, water for injection. Sodium hydroxide may be added during manufacture of BYDUREON Pen for pH adjustment.

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

BYDUREON is a registered trademark and BYETTA is a registered trademark of the AstraZeneca group of companies. All other marks are the marks of their respective owners.

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