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 with your healthcare provider about your medical condition or your treatment.

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

Serious side effects may happen in people who use 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 using 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 use 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 use BYDUREON.
   - While using 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 using 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 using 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:
  o swelling of your face, lips, tongue, or throat
  o problems breathing or swallowing
  o severe rash or itching
  o fainting or feeling dizzy
  o very rapid heartbeat

Talk to your healthcare provider before using 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: 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.

• 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 use 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 over-the-counter 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®, Jantoven®)

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.

- BYDUREON comes as a single-dose tray or as a single-dose pen. Your healthcare provider will prescribe the BYDUREON that is best for you.
- **Your healthcare provider should teach you how to use 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.
- Pay special attention to mixing BYDUREON well, as shown in the Instructions for Use.
- After injecting with the BYDUREON Pen, make sure you hold the needle in your skin for 10 seconds, to get the full dose.
- 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 use 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 use BYDUREON with or without food.
- **If you miss a dose of BYDUREON, it should be used as soon as you remember, provided the next regularly scheduled dose is due at least 3 days later.**
- **If you miss a dose of BYDUREON and the next regularly scheduled dose is due 1 or 2 days later, do not use the missed dose. Use BYDUREON on the next regularly scheduled day.**
- Do not use 2 doses of BYDUREON less than 3 days apart.