

MEDICATION GUIDE
BYDUREON BCISE® (by-DUR-ee-on B-cise)
(exenatide extended-release)
injectable suspension, for subcutaneous use

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

BYDUREON BCISE 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, BYDUREON and medicines that work like BYDUREON caused thyroid tumors, including thyroid cancer. It is not known if BYDUREON BCISE will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use BYDUREON BCISE 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 BCISE?

- BYDUREON BCISE is an injectable prescription medicine that may improve blood sugar (glucose) in adults and children who are 10 years of age and older with type 2 diabetes mellitus and should be used along with diet and exercise.
- BYDUREON BCISE is not recommended as the first choice of medicine for treating diabetes.
- BYDUREON BCISE is not for use in people with type 1 diabetes.
- BYDUREON BCISE and BYDUREON are long-acting forms of the medicine in BYETTA (exenatide). BYDUREON BCISE should not be used at the same time as BYETTA or BYDUREON.
- It is not known if BYDUREON BCISE can be used in people who have had pancreatitis.
- It is not known if BYDUREON BCISE is safe and effective for use in children younger than 10 years of age.

Do not use BYDUREON BCISE 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 have had a severe allergic reaction to exenatide or any of the ingredients in BYDUREON BCISE. See the end of this Medication Guide for a complete list of ingredients in BYDUREON BCISE. Symptoms of a severe allergic reaction with BYDUREON BCISE 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
- you have a history of low blood platelet count from using exenatide medicines (drug-induced thrombocytopenia).

Before using BYDUREON BCISE, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had problems with your pancreas or kidneys.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- are pregnant or plan to become pregnant. BYDUREON BCISE may harm your unborn baby. Tell your healthcare provider if you become pregnant while using BYDUREON BCISE. 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 BYDUREON BCISE passes into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using BYDUREON BCISE.

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

Before using BYDUREON BCISE, talk to your healthcare provider about low blood sugar and how to manage it. Especially tell your healthcare provider if you take:

- other medicines to treat diabetes, including insulin or sulfonylureas.
- a water pill (diuretic).
- a blood pressure medicine.
- warfarin.
- a pain medicine.

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 BCISE?

- Read the **Instructions for Use** that comes with BYDUREON BCISE.
- Use BYDUREON BCISE exactly as your healthcare provider tells you to.
- BYDUREON BCISE should be injected right away after you prepare your dose.
- **Your healthcare provider should show you how to use BYDUREON BCISE before you use it for the first time.**
- Caregivers should help children with mixing and injecting BYDUREON BCISE.
- BYDUREON BCISE is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. **Do not** inject BYDUREON BCISE into a muscle (intramuscularly) or vein (intravenously).
- **Use BYDUREON BCISE 1 time each week on the same day each week at any time of the day.**
- BYDUREON BCISE may be taken with or without food.
- If you miss a dose of BYDUREON BCISE, 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 BCISE 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.
- If you use a different long acting exenatide medicine and your healthcare provider switches your medicine to BYDUREON BCISE, you should start using BYDUREON BCISE at your next scheduled dose.
- **Do not** mix insulin and BYDUREON BCISE together in the same injection.
- You may give an injection of BYDUREON BCISE 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.

What are the possible side effects of BYDUREON BCISE?

BYDUREON BCISE may cause serious side effects, including:

- **See “What is the most important information I should know about BYDUREON BCISE?”**
- **inflammation of your pancreas (pancreatitis).** Stop using BYDUREON BCISE 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 BCISE 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.** In people who have kidney problems, nausea, vomiting and diarrhea may cause a loss of fluids (dehydration) which may cause kidney problems to get worse. These kidney problems include kidney failure. Dialysis or a kidney transplant may be needed.
 - **While taking BYDUREON BCISE:** Call your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.
- **stomach problems.** Other medicines like BYDUREON BCISE may cause severe stomach problems. It is not known if BYDUREON BCISE causes or worsens stomach problems.
- **serious allergic reactions.** Stop using BYDUREON BCISE and get medical help right away if you have any symptoms of a serious allergic reaction, including itching, rash, or difficulty breathing. See **“Who should not use BYDUREON BCISE?”**
- **low blood platelet count (drug-induced thrombocytopenia).** BYDUREON BCISE 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 BYDUREON BCISE and call your healthcare provider right away if you have unusual bleeding or bruising.** Your blood platelet count may continue to be low for about 10 weeks after stopping BYDUREON BCISE.
- **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.
- **gallbladder problems.** Gallbladder problems have happened in some people who take BYDUREON or other medicines like BYDUREON. Tell your healthcare provider right away if you get symptoms of gallbladder problems which may include: pain in the right or middle upper stomach area, nausea and vomiting, fever, or your skin or the white part of your eyes turns yellow.

The most common side effects of BYDUREON BCISE may include a bump (nodule) at the injection site and nausea. Nausea is most common when you first start using BYDUREON BCISE 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 BCISE.

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

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

General information about the safe and effective use of BYDUREON BCISE.

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

What are the ingredients in BYDUREON BCISE?

Contents of the powder:

Active ingredient: exenatide.

Inactive ingredients: polylactide-co-glycolide and sucrose.

Contents of liquid (diluent):

Inactive Ingredients: medium chain triglycerides.

BYDUREON, BCISE and BYETTA are trademarks of the AstraZeneca group of companies. All other marks are the marks of their respective owners.

Manufactured for:

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By:

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For more information about BYDUREON BCISE, go to www.BYDUREONBCISE.com or call 1-800-236-9933.