

BYDUREON BCise (Subcutaneous)

Generic name: exenatide [*ex-EN-a-tide*]

Brand names: Bydureon, BYDUREON BCise, Byetta

Drug class: GLP-1 Agonists (Incretin Mimetics)

Medically reviewed by Drugs.com. Last updated on Jan 8, 2025.

Subcutaneous route(Suspension, Extended Release)

Exenatide extended-release causes an increased incidence in thyroid C-cell tumors at clinically relevant exposures in rats compared to controls. It is unknown whether exenatide extended-release causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of exenatide extended-release-induced rodent thyroid C-cell tumors has not been determined.

Exenatide extended-release is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of exenatide extended-release and inform them of symptoms of thyroid tumors (eg, mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for detection of MTC in patients treated with exenatide extended-release

Uses for BYDUREON BCise

Exenatide injection is used together with diet and exercise to treat type 2 diabetes.

This medicine is available only with your doctor's prescription.

Before using BYDUREON BCise

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of *Byetta®* in children and *Bydureon® Bcise®* in children younger than 10 years of age. Use of *Bydureon®* is not recommended in children. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of exenatide injection in the elderly. However, elderly patients are more likely to have kidney problems, which may require caution and an adjustment in the dose for patients receiving exenatide injection.

Breast Feeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Abiraterone Acetate
- Chloroquine
- Chlorothiazide
- Chlorthalidone
- Ciprofloxacin
- Delafloxacin
- Enoxacin
- Furosemide
- Gatifloxacin

- Gemifloxacin
- Grepafloxacin
- Hydrochlorothiazide
- Hydroflumethiazide
- Hydroxychloroquine
- Indapamide
- Lanreotide
- Levofloxacin
- Lomefloxacin

- Metolazone
- Moxifloxacin
- Norfloxacin
- Octreotide
- Ofloxacin
- Pasireotide

- Polythiazide
- · Somatrogon-ghla
- Sparfloxacin
- Thioctic Acid
- Triamterene
- Trovafloxacin

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Acebutolol
- Atenolol
- Betaxolol
- Bisoprolol
- Carteolol
- Carvedilol
- Celiprolol
- Digoxin
- Esmolol
- Insulin
- Insulin Aspart, Recombinant
- Insulin Bovine
- Insulin Degludec
- Insulin Detemir
- Insulin Glargine, Recombinant
- Insulin Glulisine

- Insulin Lispro, Recombinant
- Labetalol
- Levobunolol
- Metipranolol
- Metoprolol
- Nadolol
- Nebivolol
- Oxprenolol
- Penbutolol
- Pindolol
- Practolol
- Propranolol
- Semaglutide
- Sotalol
- Timolol
- Warfarin

Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Diabetic ketoacidosis (ketones in the blood) or
- Type 1 diabetes—Should not be used in patients with these conditions. Insulin is needed to control these conditions.
- Drug induced immune-mediated thrombocytopenia, history of or
- Gastroparesis (stomach does not empty food normally) or
- · Kidney disease, severe or
- Multiple endocrine neoplasia syndrome type 2 (MEN 2) or
- · Stomach or bowel disease, severe or
- Thyroid cancer, history of—Should not be used in patients with these conditions.
- · Gallstones or
- Kidney disease (including kidney transplant) or
- Pancreatitis (inflammation of the pancreas), history of or
- Thyroid tumor—Use with caution. May make these conditions worse.

Proper use of BYDUREON BCise

Bydureon® BCise® should not be the first medicine you use to treat your condition. It is meant to be used only after you have tried other medicines that have not worked or have caused unwanted side effects.

When you start using this medicine, it is very important that you check your blood sugar often, especially before and after meals and at bedtime. This will help lower the chance of having very low blood sugar.

Carefully follow the special meal plan your doctor gave you. This is the most important part of controlling your diabetes, and is necessary if the medicine is to work properly. Also, exercise regularly and test for sugar in your blood or urine as directed.

Use only the brand of this medicine that your doctor prescribed. Different brands may not work the same way. Bydureon® and Bydureon® BCise®are extended-release forms of Byetta®. If you are changing from Byetta® to Bydureon® or Bydureon® BCise®, you should stop using Byetta®. Do not use these medicines together.

Byetta® comes in a prefilled pen that you will use to inject it. Each pen contains enough medicine for 60 doses.

Bydureon® comes in a single-dose tray containing: 1 vial of exenatide powder, 1 vial connector, 1 prefilled diluent syringe, and 2 needles. Do not substitute needles or any other components in the tray.

Bydureon® BCise® is available as a single-dose autoinjector.

This medicine should come with a Medication Guide and patient instructions or Pen User Manual. Read and follow these instructions carefully. Ask your doctor if you have any questions.

You will be using exenatide at home. Your doctor will teach you how the injections are to be given. Be sure you understand exactly how the medicine is to be injected.

This medicine is given as a shot under the skin of your stomach, thighs, or upper arm. Use a different body area each time you give yourself a shot. Keep track of where you give each shot to make sure you rotate body areas.

Allow *Byetta®* to warm to room temperature before you inject it. If the medicine in the pen has changed color, looks cloudy, or if you see particles in it, do not use it.

Use *Bydureon®* immediately once the powder has been dissolved and transferred to the syringe. Always inject *Bydureon®* and insulin separately. You may inject these 2 medicines in the same body area but they should not be injected next to each other.

Allow the *Bydureon® BCise® autoinjector* to warm to room temperature for 15 minutes before using it. Shake it well for 15 seconds to mix it evenly. The mixture should appear white to off-white or cloudy sand does not contain any particles in it.

Use a new needle each time you inject your medicine.

Tell your doctor if you are using birth control pills or an antibiotic. These medicines should be taken at least 1 hour before you use. *Byetta®*.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For type 2 diabetes:
 - For injection dosage form (extended-release suspension, Bydureon®):
 - Adults—2 milligrams (mg) injected under the skin once every 7 days, at any time of the day, with or without meals.
 - Children—Use is not recommended.
 - For injection dosage form (extended-release suspension, Bydureon® BCise®):
 - Adults—2 milligrams (mg) injected under the skin once every 7 days, at any time of the day, with or without meals.
 - Children—Use is not recommended.
 - For injection dosage form (solution, Byetta®):
 - Adults—At first, 5 micrograms (mcg) injected under the skin 2 times a day at any time within the 60-minute period before the morning and evening meals (or before the 2 main meals of the day, about 6 hours or more apart). Your doctor may adjust your dose after the first month of treatment to 10 mcg 2 times a day.
 - Children—Use and dose must be determined by your doctor.

Missed Dose

If you miss a dose of this medicine, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

For patients using *Bydureon®* or *Bydureon® BCise®*: If you miss a dose of this medicine, use it as soon as you remember, as long as your next dose is due at least 3 days later. If you miss a dose and the next dose is due 1 or 2 days later, skip the missed dose and go back to your regular dosing schedule. Do not use 2 doses of this medicine less than 3 days apart.

For patients using *Byetta®*: Do not use this medicine after you eat if you forget to use it before the meal. Wait until 1 hour before your next meal and use the medicine at that time. Do not use extra medicine to make up for a missed dose.

Storage

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store in the refrigerator. Do not freeze.

For patients using *Bydureon®*: Store your medicine in the refrigerator in its original carton, and protect it from light. Do not freeze this medicine, and do not use it if it has been frozen. You may also store this medicine at room temperature for up to 4 weeks.

For patients using the *Bydureon® BCise® autoinjector*: Store the autoinjector *flat* in the refrigerator in its original carton, and protect it from light. You may also store this medicine at room temperature for up to 4 weeks. Keep it always clean and away from any spills.

For patients using Byetta®:

- Store your new, unused medicine pen in the refrigerator in its original carton, and protect it from light. Do not freeze this medicine, and do not use the medicine if it has been frozen. You may store the opened medicine pen in the refrigerator or at room temperature for 30 days. Throw away any unused medicine after 30 days.
- Remove the needle from the pen before storing Byetta®. This prevents leaking of the remaining medicine and prevents air bubbles from forming in the pen.

Throw away used needles in a hard, closed container where the needles cannot poke through. Keep this container away from children and pets.

Detailed Bydureon BCise dosage information

Precautions while using BYDUREON BCise

Never share medicine pens or single-dose trays with others under any circumstances. It is not safe for one pen to be used for more than one person. Sharing needles, pens, or single-dose trays can result in transmission of infection.

It is very important that your doctor check your progress at regular visits to make sure that this medicine is working properly. Blood and urine tests may be needed to check for unwanted effects.

Tell your doctor if you are also using insulin. You should not use prandial insulin (eg, Apidra®, Lantus®) while you are using this medicine. *Using these medicines together may cause unwanted effects*.

It is very important to carefully follow any instructions from your health care team about:

- Alcohol—Drinking alcohol may cause severe low blood sugar. Discuss this with your health care team.
- Other medicines—Do not take other medicines during the time you are using exenatide unless they have been discussed with your doctor. This especially includes nonprescription medicines

such as aspirin, and medicines for appetite control, asthma, colds, cough, hay fever, or sinus problems.

- Counseling—Other family members need to learn how to prevent side effects or help with side
 effects if they occur. Also, diabetic patients may need special counseling about diabetes medicine
 dosing changes that might occur because of lifestyle changes, such as changes in exercise and
 diet. Furthermore, counseling on contraception and pregnancy may be needed because of the
 problems that can occur during pregnancy in patients with diabetes.
- Travel—Keep a recent prescription and your medical history with you. Be prepared for an emergency as you would normally. Make allowances for changing time zones and keep your meal times as close as possible to your usual meal times.

In case of emergency—There may be a time when you need emergency help for a problem caused by your diabetes. You need to be prepared for these emergencies. It is a good idea to wear a medical identification (ID) bracelet or neck chain at all times. Also, carry an ID card in your wallet or purse that says that you have diabetes and a list of all of your medicines.

This medicine may increase the risk of having thyroid tumors. Tell your doctor right away if you have a lump or swelling in your neck or throat and if you use *Bydureon®* or *Bydureon®* BCise®. Also tell your doctor if you have trouble swallowing or breathing, or if your voice gets hoarse.

Pancreatitis (swelling of the pancreas) may occur while you are using this medicine. Check with your doctor right away if you have sudden and severe stomach pain, chills, constipation, nausea, vomiting, fever, or lightheadedness.

This medicine may cause serious allergic reactions, including anaphylaxis and angioedema, which can be life-threatening and require immediate medical attention. Check with your doctor right away if you have a rash, itching, hoarseness, trouble breathing, trouble swallowing, or any swelling of your hands, face, mouth, or throat while you are using this medicine.

This medicine may lower the number of platelets in your blood, causing your body to not form blood clots. This may lead to serious bleeding and death. Call your doctor right away if you have unusual bleeding or bruising. Your blood platelet count may continue to be low for about 10 weeks after stopping this medicine.

Call your doctor right away if you notice any of these side effects at the injection site, including depressed or indented skin, blue-green to black skin discoloration, or pain, redness, or peeling of the skin.

This medicine does not cause hypoglycemia (low blood sugar). However, low blood sugar can occur when you use exenatide with other medicines, such as insulin or sulfonylureas, that can lower blood

sugar. Low blood sugar also can occur if you delay or miss a meal or snack, exercise more than usual, drink alcohol, or cannot eat because of nausea or vomiting.

Symptoms of low blood sugar include: anxiety, behavior change similar to being drunk, blurred vision, cold sweats, confusion, cool, pale skin, difficulty with thinking, drowsiness, excessive hunger, fast heartbeat, headache (continuing), nausea, nervousness, nightmares, restless sleep, shakiness, slurred speech, or unusual tiredness or weakness.

If symptoms of low blood sugar occur, eat glucose tablets or gel, corn syrup, honey, or sugar cubes, or drink fruit juice, non-diet soft drink, or sugar dissolved in water to relieve the symptoms. Also, check your blood for low blood sugar. Glucagon is used in emergency situations when severe symptoms including seizures or unconsciousness occur. Have a glucagon kit available, along with a syringe and needle, and know how to use it. Members of your family should also know how to use it.

Hyperglycemia (high blood sugar) may occur if you do not take enough or skip a dose of your antidiabetic medicine, overeat or do not follow your meal plan, have a fever or infection, or do not exercise as much as usual.

Symptoms of high blood sugar include: blurred vision, drowsiness, dry mouth, flushed, dry skin, fruit-like breath odor, increased urination (frequency and amount), ketones in the urine, loss of appetite, stomachache, nausea or vomiting, tiredness, trouble breathing (rapid and deep), unconsciousness, or unusual thirst.

If symptoms of high blood sugar occur, check your blood sugar level and then call your doctor for instructions.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects of BYDUREON BCise

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Incidence not known

- Agitation
- bleeding, blistering, burning, coldness, discoloration of the skin, feeling of pressure, hives, infection, inflammation, itching, lumps, numbness, pain, rash, redness, scarring, soreness, stinging, swelling, tenderness, tingling, ulceration, or warmth at the injection site
- bloated or feeling of fullness
- chest tightness

- chills
- confusion
- constipation
- cough
- · dark urine
- · decreased awareness or responsiveness
- · decreased urination or urine output
- depression
- · difficulty with swallowing
- dizziness
- dry mouth
- fainting
- · fast heartbeat
- fever
- headache
- · hives or welts, itching, or skin rash
- hostility
- · increase in heart rate
- indigestion
- irritability
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or genitals
- lightheadedness
- · loss of appetite
- · loss of consciousness
- muscle twitching
- nausea
- pains in the stomach, side, or abdomen, possibly radiating to the back
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue

- rapid breathing
- · rapid weight gain
- seizures
- severe sleepiness
- · sunken eyes
- · swelling of the face, ankles, or hands
- thirst
- · unusual bleeding or bruising
- unusual drowsiness, dullness, tiredness, weakness, or feeling of sluggishness
- vomiting
- wrinkled skin
- · yellow eyes or skin

Get emergency help immediately if any of the following symptoms of overdose occur:

Symptoms of overdose

- Anxiety
- blurred vision
- · cold sweats
- · cool, pale skin
- · increased hunger
- nervousness
- nightmares
- · severe vomiting
- shakiness
- slurred speech

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health

care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- Belching
- diarrhea
- · feeling jittery
- heartburn
- stomach discomfort or upset

Less common

- · Decreased appetite
- · increased sweating
- · lack or loss of strength

Incidence not known

- Change in taste
- · excess air or gas in the stomach or bowels
- hair loss, thinning of hair
- loss of taste
- passing gas
- · pressure in the stomach
- · rash with flat lesions or small raised lesions on the skin
- · redness of the skin
- sleepiness or unusual drowsiness
- · swelling of the stomach area

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

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



Bydureon BCise side effects (more detail)

Related/similar drugs

Ozempic

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Reviews & ratings

6.7 / 10

1,484 Reviews

Rybelsus

Rybelsus tablets are used to improve blood sugar control in adults with type 2 diabetes, and may ...

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Review

8.6 / 10

Commonly used brand name(s)

In the U.S.

- Bydureon
- BYDUREON BCise
- Byetta

Available Dosage Forms:

- Solution
- Suspension, Extended Release

Therapeutic Class: Antidiabetic

Pharmacologic Class: Glucagon-Like Peptide-1 Receptor Agonist

Frequently asked questions

- How long does it take for Bydureon Bcise to take effect?
- How and where is the Bydureon injection given?
- How do you use the Bydureon Bcise autoinjector?
- How long can Bydureon be unrefrigerated?
- How do you use the Bydureon pen?
- How does Bydureon work?

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.