

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**BYDUREON®
exenatide for extended-release injectable suspension**

Read this carefully before you start taking **BYDUREON** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BYDUREON**.

Serious Warnings and Precautions

Do NOT use BYDUREON if you:

- or a family member has ever had medullary **thyroid** cancer (MTC).
- have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). This is a disease where people have tumours in more than one gland in their body.

In rats, BYDUREON causes a higher rate of thyroid tumours. It is not known if BYDUREON causes thyroid tumours, including MTC, in people.

What is BYDUREON used for?

BYDUREON along with diet and exercise is used to improve control of blood sugar levels in adults with type 2 diabetes.

BYDUREON can be used:

- alone, if you cannot take metformin,
OR
- in combination with these drugs. The combination is used when these drugs no longer provide enough control of blood sugar levels on their own.
 - metformin
 - a sulfonylurea (SU)
 - or metformin and a SU

How does BYDUREON work?

BYDUREON helps your body release more insulin when your blood sugar is high. This helps to improve your blood sugar control.

What are the ingredients in BYDUREON?

Medicinal ingredients: extended release exenatide

Non-medicinal ingredients: carboxymethylcellulose sodium, dibasic sodium phosphate heptahydrate, monobasic sodium phosphate monohydrate, poly (D,L-lactide-co-glycolide),

polysorbate 20, sodium chloride, sucrose, water for injection.

BYDUREON is supplied as:

A kit which contains:

- 4 single dose pens
- One extra needle (23 gauge, 9/32")
- Patient Medication Information
- Instructions for Use

Each pen contains:

- 2 mg exenatide (as a white to off-white powder) in the front chamber of the pen injector
- Sufficient diluent filled in the rear chamber of the glass cartridge injector pen to deliver 0.65 mL after reconstitution
- One injection needle (23 gauge, 9/32")

Do not use BYDUREON if you:

- are allergic to exenatide or to any of the ingredients in this drug.
- have severe kidney disease or are on dialysis.
- have diabetic ketoacidosis. This is an accumulation of ketones in the blood and urine.
- have type 1 diabetes.
- are pregnant or planning to have a baby. It is not known if BYDUREON will harm your unborn baby. Women who can have children should use effective means of birth control while they are taking BYDUREON. BYDUREON should be stopped at least 3 months before planning to become pregnant.
- are under 18 years old.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BYDUREON. Talk about any health conditions or problems you may have, including if you:

- are taking other drugs to control blood sugar.
- are taking a blood thinner such as warfarin.
- have a high heart rate (fast pulse).
- have a condition called heart block.
- have any heart disease, such as angina, history of a heart attack, or heart rhythm disturbances.
- are receiving treatment with an SU. Examples are glyburide, gliclazide, glimepride. These types of drugs can increase the risk of having low blood sugar if used in combination with BYDUREON.
- have severe problems with your stomach (gastroparesis) or food digestion. BYDUREON slows the emptying of your stomach so food passes more slowly.
- have severe vomiting and/or diarrhea and/or dehydration.
- have a history of problems with your pancreas, stones in your gallbladder (gallstones), alcohol abuse, or high levels of fat in your blood.
- have kidney problems or a kidney transplant.
- are breast feeding or plan to breastfeed. It is not known if BYDUREON passes into breast

milk.

- are over 65 years old.

Other warnings you should know about:

When using BYDUREON with an SU take precautions to avoid having low blood sugar while driving or using machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BYDUREON:

- an SU such as glyburide, gliclazide, glimepiride. Taking BYDUREON with an SU can make your blood sugar too low.
- certain other kinds of drugs used to control blood sugar, including all drugs that contain exenatide.
- drugs that increase heart rate or that affect your heart rhythm.
- other drugs taken by mouth.
- a birth control pill (oral contraceptive).
- blood thinner (warfarin).
- heart medication (digoxin).
- blood pressure medication (lisinopril).
- cholesterol medication (lovastatin).

How to take BYDUREON:

Your doctor or pharmacist should give you training before you inject BYDUREON. You should also read the “Instructions for Use” included at the end of this Patient Medication Information. A copy of the “Instructions for Use” is also included in the product packaging. These instructions will give you details on how to use and inject BYDUREON.

Use BYDUREON exactly as instructed by your doctor. Never take more than the dose your doctor has told you to use.

For subcutaneous use only. BYDUREON is to be injected under the skin (subcutaneous injection) of your stomach area (abdomen), upper leg (thigh), or upper arm. If you inject in the same body part, you should choose a different spot each week. DO NOT inject through clothing.

Do not take BYDUREON if it is discolored, contains solid particles or if there are any signs of leakage. Look through the Inspection Window. The solution should be clear.

After the BYDUREON powder is completely suspended in the diluent, it should be injected right away. Follow the “Instructions for Use” to make sure that BYDUREON is completely suspended before you inject. Now the solution should have no lumps and be uniformly cloudy.

BYDUREON must not be injected into a vein or muscle.

Do not share BYDUREON with another person. Do not reuse needles or other parts of the pen injector.

Do not substitute needles or any other parts in the pen injector.

Do not mix BYDUREON with any other medicines.

If you stop taking BYDUREON, tell your healthcare professional. Do not start taking other drugs, vitamins, mineral supplements or alternative medicines on your own. This includes other drugs to treat diabetes. BYDUREON drug levels, effects and side effects will slowly go down in your body. This continues for about 10 weeks after you stop using it.

Recommended Adult dose:

2 mg subcutaneous injection once every seven days. The dose can be administered at any time of day, with or without meals.

When you first take BYDUREON with an SU, your doctor might lower the dose of the SU.

Overdose:

Too much BYDUREON can give you nausea, vomiting or make you feel like you have low blood sugar.

If you think you have taken too much BYDUREON, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of BYDUREON, you should take it as soon as you remember if it is within 3 days after the missed dose. You can take your next dose at your usual weekly time.

If it has been longer than 3 days after the missed dose, skip the dose and wait to take BYDUREON at your next usual weekly time. Do not take an extra dose of BYDUREON to make up for your missed dose.

What are possible side effects from using BYDUREON?

These are not all the possible side effects you may feel when taking BYDUREON. If you experience any side effects not listed here, contact your healthcare professional. Please also see the Serious Warnings and Precautions box.

Side effects may include:

- nausea, vomiting, diarrhea, constipation, pain in stomach area (abdomen), decreased appetite
- injection site reactions such as lump, redness, itchiness bruising and/or pain
- dizziness, headache, common cold, cough
- joint and muscle pain

- weight loss. If you are concerned talk to your health care professional
- rash

BYDUREON can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Hypoglycemia (low blood sugar) especially if you are also taking an SU. You may have headaches, feel sleepy, weak, dizzy, confused, hungry, jittery, or sweaty. Feel like your heart is beating fast.	✓		
UNCOMMON			
Pancreatitis (swelling of the pancreas): long periods of pain in the stomach and/or intestine area may go around to your back. You may also vomit.			✓
Dehydration. (It can be from nausea, vomiting and/or diarrhea, or not taking enough liquids by mouth): If this happens while on BYDUREON it may cause new or worsening problems with kidney function. This includes kidney failure.	✓		
Increase heart rate or changes in heart rhythm: dizziness, fainting. Feel a rapid, pounding, or irregular heartbeat. They are more likely if you, have heart disease, take certain other drugs, or are more than 65 years old.		✓	
Injection Site Reactions: Swelling, hardness, itching, redness, dark discoloration or bruising. This can be with or	✓		

Serious side effects and what to do about them			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
without lumps under the skin. There can be intense pain, pus, or an open wound, fever and fatigue. Surgery may be required.			
RARE			
Angioedema or Severe Allergic Reactions, including Anaphylaxis: severe rash, hives, or itching. Sudden swelling of the face, lips, tongue or throat. Difficulty breathing or swallowing. Fainting and a very fast heartbeat.			✓
Kidney Disorders: nausea, vomiting, diarrhea. Muscle cramps. Swelling of the legs, ankles, feet, face and/or hands. Shortness of breath due to extra fluid on the lungs. More frequent urination, or in greater amounts than usual, with pale urine. Or, less frequent urination, or in smaller amounts than usual, with dark coloured urine.			✓
Thyroid Cancer: a lump or swelling in your neck, hoarseness, or trouble swallowing.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store BYDUREON in the original carton in a refrigerator at 2°C to 8°C. Protect from light. Do not freeze. Throw away any BYDUREON that has been frozen.
- BYDUREON can be stored at room temperature up to 30°C for 4 weeks if required.
- BYDUREON should not be used after the expiration date printed on the product packaging (carton and pen injector).
- Properly dispose of BYDUREON, with the needle attached, in a puncture-resistant container, or as directed by your healthcare professional. Do not try to recap or reuse the needle.
- Keep BYDUREON, the needles and all medicines out of reach and sight of children and pets.

If you want more information about BYDUREON:

- Talk to your healthcare professional
- Find the current full Product Monograph that is prepared for healthcare professionals and includes the current Patient Medication Information and Instructions for Use by visiting the [Health Canada website](http://hc-sc.gc.ca/index-eng.php) (<http://hc-sc.gc.ca/index-eng.php>); the AstraZeneca website: www.astrazeneca.ca, or by calling AstraZeneca Canada Inc. at:
 - 1-800-668-6000 (Customer Inquiries)
 - 1-800-461-3787 (Renseignements).

NOTE: This PATIENT MEDICATION INFORMATION leaflet provides you with the most current information at the time of printing.

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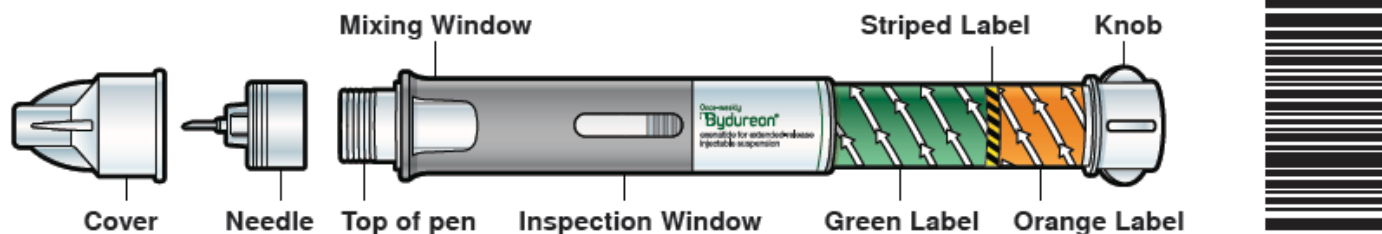
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Important Instructions for Use, read carefully

How to use [®]BYDUREON[®]

(exenatide for extended-release injectable suspension)



Prior to using BYDUREON you should be trained on its proper use by a healthcare professional.

Read these instructions 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. Unless a trained person can help, BYDUREON is not recommended for people who are blind or cannot see well.

Step 1: Prepare Your Pen

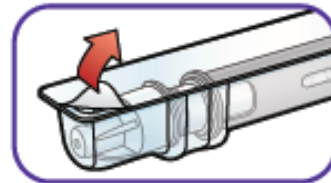
Let your pen warm up. Remove one pen from the refrigerator and let it stand at room temperature for at least 15 minutes. **DO NOT** use a pen past its expiration date.

WAIT

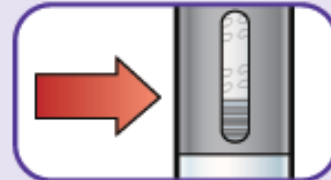


Be sure to wash your hands while the pen is warming up.

Open the tray by pulling on the corner tab. Then remove the pen and needle. **DO NOT** use your pen or needle if any parts are broken or missing.



Check the liquid inside the inspection window. It should be clear and free of particles. It's okay if you see bubbles.



Completely peel off the paper tab from the needle cover.

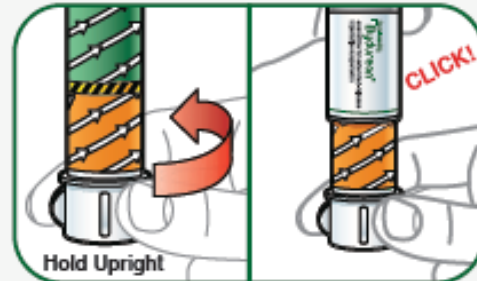


Attach the needle to the pen by pushing and screwing it onto the top of the pen until it is tight. **DO NOT** remove the needle cover yet.



Step 2: Mix Your Dose

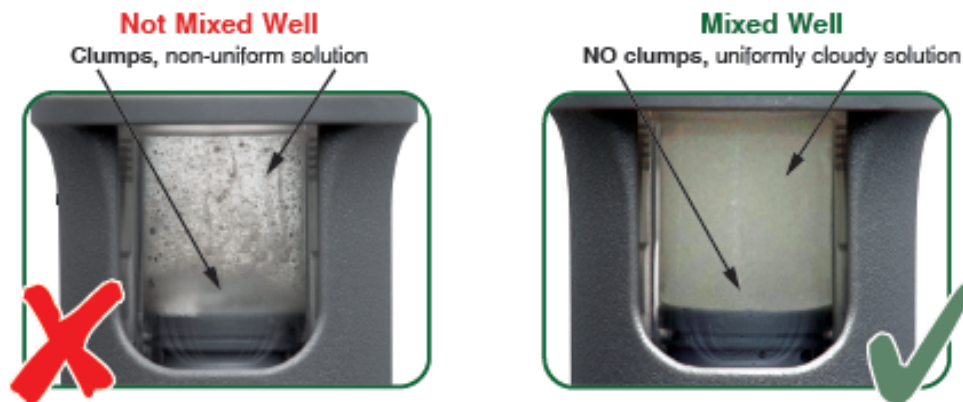
Combine the medicine. While holding the pen straight up, **slowly** turn the knob. **STOP** when you hear the click and the green label disappears.



Firmly tap the pen to mix. Hold the pen by the end with the orange label and **tap the pen firmly against the palm of your hand.** **WITHOUT** twisting the knob, **ROTATE** the pen every few taps. You may need to tap 80 times or more.



Check the mix. Hold the pen up to the light and look through **both sides of the mixing window.** The solution should have **NO CLUMPS** and be uniformly cloudy.



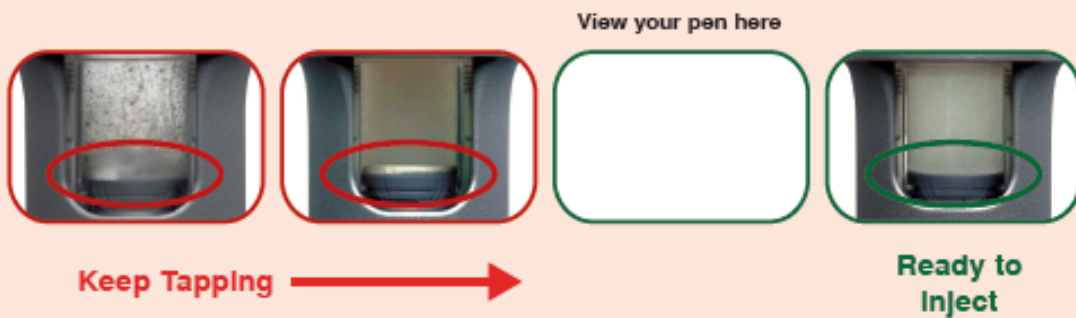
To get your full dose the medicine must be mixed well.
If it's not mixed well, tap longer and more firmly.



DO NOT proceed unless
your medicine is mixed well

To get your full dose the medicine must be mixed well.
If it's not mixed well, tap longer and more firmly.

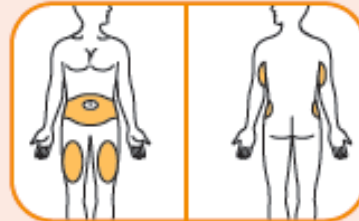
Compare both sides of the mixing window to the photos below
by holding the pen against the page. Pay attention to the **bottom surface**.
If you **don't see clumps** you are ready to inject.



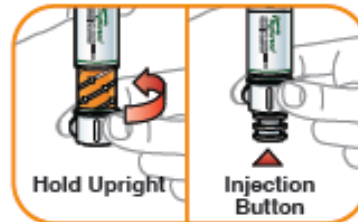
Step 3: Inject Your Dose

IMPORTANT Once the medicine is mixed well, you must inject the dose immediately. You cannot save it for later use.

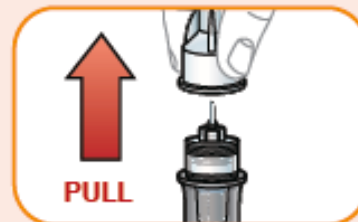
Choose your Injection site in either your stomach, thigh or back of the arm. Each week you can use the same area of your body but choose a different injection site in that area. **Gently clean the area** with soap and water or an alcohol swab.



Twist knob to release Injection button. While holding the **pen straight up**, turn the knob until the orange label disappears and the injection button is released. **DO NOT** push the injection button yet.



Remove the needle cover by pulling straight off. **DO NOT** twist. You may see a few drops of liquid on the needle or in the cover.



Inject the medicine. **DO NOT** inject through clothing. Lift or remove clothing. Insert the needle into your skin. Press the injection button with your thumb until you hear a click. **Hold for 10 seconds** to make sure you get the full dose.



Properly dispose of your pen, with the needle attached, in a puncture-resistant container. **DO NOT** try to recap or reuse the needle.



Common Questions and Answers

1. How do I know that the medicine is mixed well?

The medicine is mixed well when the liquid looks cloudy from both sides of the window. You should not see any clumps in the liquid. It may help to hold the pen up to the light to see in the window. If you see clumps of any size keep tapping the pen firmly against the palm of your hand until mixed.

2. I am having trouble mixing my dose. What should I do?

Remember, before preparing your dose, leave the pen out of the refrigerator for at least 15 minutes. This will let the pen warm up to room temperature. It will be easier to mix the medicine if the pen is at room temperature.

Be sure you are holding the pen at the end with the knob and the orange label. This will help you grip the pen better and tap it more firmly against your palm.

It may also help to tap the mixing window on both sides against your palm. If you see any clumps, keep tapping.

3. After I mix the medicine, how long can I wait before taking the injection?

You must inject your dose of BYDUREON right after mixing it. If you do not inject BYDUREON right

away, small clumps of medicine may form in the pen and you may not get your full dose.

4. I'm ready to inject my dose. What should I do if I see air bubbles in the pen?

It is normal for air bubbles to be in the pen. BYDUREON is injected into your skin (subcutaneously). Air bubbles will not harm you or affect your dose with this type of injection.

5. What should I do if I cannot push the injection button all the way in when trying to inject my dose?

Check that you have fully screwed on the pen needle. Also be sure you twisted the knob until it stopped, the orange label disappeared, and the injection button appears.

If you still cannot push the button in, this may mean that the needle is clogged. Remove the needle from your skin and replace it with the spare needle from the carton. Review how to attach the needle. Then choose a different injection site and finish taking the injection.

If you still cannot push the button all the way in, remove the needle from your skin. Use a puncture-resistant container to throw away the pen with the needle still attached.

6. How do I know if I injected my full dose?

To be sure you get your full dose, press the injection button with your thumb until you hear a click. After the click, continue to hold the needle in your skin for 10 seconds. This will allow enough time for all the medicine to go from the pen to under your skin.

7. How do I dispose of BYDUREON?

Dispose of your pen in a Sharps container.

Be careful when discarding the pen after use. Sharps containers are special puncture-resistant disposable bins that can be purchased at many pharmacies. If you do not have a Sharps container, you may dispose of your used pen in a puncture-resistant hard plastic or metal container that can be closed with a lid or cap, such as a laundry detergent bottle or coffee can. Do not use glass or clear plastic containers.

Always keep your Sharps container out of reach of children and animals. Ask your doctor, nurse, or pharmacist about provincial and local laws regarding the proper disposal of medical products that contain needles. Do not throw away your used prefilled pens in your household trash or recycling bins.

To make sure you receive your full dose, follow these do's and don'ts:

- **DO** take the pen out of the refrigerator 15 minutes before you inject. Letting the pen warm up will make the medicine easier to mix
- **DO** hold the pen in the correct orientation throughout the injection process
- **DON'T** inject unless the medicine is well mixed with no clumps. (It should look cloudy)
- **DON'T** remove the needle from the injection site until 10 seconds after the click

Inside your BYDUREON carton are 4 single-dose pens. Each pen contains BYDUREON and 1 custom needle. The carton also contains an extra needle in case you need it.

How to Store BYDUREON

- Store your pens in the refrigerator at 2°C to 8°C.
- If needed, you can keep a pen out of the refrigerator at room temperature (not to exceed 30°C) for up to 4 weeks
- Protect pens from light until you are ready to prepare and use your dose
- Do not freeze the pens
- Do not use pens past the expiration date shown on the product packaging.
- Keep BYDUREON, and all medicines, out of the reach of children

For Questions or More Information

- **Talk with your healthcare provider**
- **Read the Patient Medication Information that came with your pens.** The Patient Medication Information can help answer your questions about BYDUREON, such as what it is used for, possible side effects, and when to take BYDUREON.
- **Read the Common Questions and Answers in this Instructions for Use.**
- **Visit www.astrazeneca.ca**
- **Questions or concerns: 1-800-668-6000**

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