PART III: CONSUMER INFORMATION

BYETTA®
exenatide injection

This leaflet is part III of a three-part "Product Monograph" published when BYETTA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BYETTA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What BYETTA is used for:
BYETTA is used to improve blood sugar control in adults with type 2 diabetes in combination with metformin and/or a sulfonylurea when metformin and/or a sulfonylurea plus diet and exercise have failed to adequately control blood sugar levels. BYETTA is also used to improve blood sugar control in adults with type 2 diabetes in combination with insulin glargine (with or without metformin) when insulin glargine (with or without metformin) plus diet and exercise have failed to adequately control blood sugar levels. Continue to follow your diet and exercise plan.

What BYETTA does:
BYETTA helps your body release more insulin when your blood sugar is high. This helps to improve your blood sugar control.

When BYETTA should not be used:
- Do not use BYETTA if you are allergic to exenatide or any of the other ingredients in BYETTA listed in the "nonmedicinal ingredients" section below.
- Do not use BYETTA if you have severe kidney disease or are on dialysis.
- Do not use BYETTA if you have diabetic ketoacidosis (accumulation of ketones in the blood and urine).
- Do not use BYETTA if you have type 1 diabetes.

What the medicinal ingredient is:
exenatide

What the nonmedicinal ingredients are:
m-cresol, mannitol, glacial acetic acid, sodium acetate trihydrate and water for injection.

What dosage forms BYETTA comes in:
BYETTA is a solution for injection under the skin (subcutaneous injection) and is available as prefilled injection pens. There are two prefilled pens that provide 60 doses of either 5 µg or 10 µg exenatide per dose.

WARNINGS AND PRECAUTIONS

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving BYETTA. Pancreatitis can be a serious, potentially life-threatening medical condition. (See below - SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM.)

There is no experience with BYETTA in children and adolescents less than 18 years and therefore, use of BYETTA is not recommended in this age group.

BYETTA may increase heart rate or cause changes in heart rhythm. Rarely drugs with these effects could result in dizziness, palpitations (a feeling of rapid, pounding, or irregular heart beat), fainting, or death. These heart rhythm changes are more likely if you have heart disease or if you are taking certain other drugs. In general, people more than 65 years in age are at higher risk. See SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM. If you experience dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should seek immediate medical attention.

BEFORE you use BYETTA talk to your doctor or pharmacist if you:
- Have severe problems with your stomach (gastroparesis) or food digestion. BYETTA slows stomach emptying so food passes more slowly through your stomach.
- Have severe vomiting and/or diarrhea and/or dehydration.
- Have a history of pancreatitis (inflammation of the pancreas), stones in your gallbladder (gallstones), a history of alcoholism, or high blood triglyceride levels.
- Are receiving treatment with a sulfonylurea (e.g. glyburide, gliclazide, glimepiride) or insulin since these types of drugs can increase the risk of hypoglycemia (low blood sugar) if used in combination with BYETTA. Take precautions to avoid low blood sugar while driving or using machinery.
- Have had kidney disorder or kidney transplant.
- Are pregnant or planning to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have current or history of heart failure or other heart disease, such as angina or heart rhythm disturbances, or if you have ever had a myocardial infarction (heart attack).
- Have a personal history of fainting spells.
- Have high heart rate (fast pulse) or a condition called heart block.
- Have electrolyte disturbances (e.g., low blood potassium or magnesium levels) or conditions that could lead to electrolyte disturbances (e.g., vomiting, diarrhea, dehydration).
- Or a member of your family have ever had medullary thyroid cancer.

- Have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Also talk to your doctor or pharmacist before you use BYETTA if you:

- have been diagnosed with pituitary or adrenal failure
- have any eating disorders, are on a special diet, or often skip meals
- exercise regularly or intensely
- drink alcohol excessively

These conditions may increase your risk of low blood sugar if you take BYETTA.

Your blood sugar may get too high (hyperglycemia) if you have fever, infection, surgery, or trauma (stress conditions). In such cases contact your doctor as your medication may need to be adjusted.

BYETTA should not be injected into a vein or muscle.

The use of BYETTA with rapid-acting or short-acting insulin is not recommended.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.

In particular, tell your doctor or pharmacist if you are taking:

- a birth control pill (oral contraceptive), this medication should be taken at least 1 hour before taking BYETTA
- an antibiotic, this medication should be taken at least 1 hour before taking BYETTA
- warfarin (blood thinner)
- digoxin (heart medication)
- lisinopril (blood pressure medication)
- acetaminophen (pain and fever medication)
- lovastatin (cholesterol medication)
- any of the following drugs that may increase the risk of heart rhythm disturbances:
  - drugs to treat heart rhythm disturbances
  - antivirals to treat HIV infection
  - diuretics (water pills)
  - drugs to treat hypertension (high blood pressure)
  - drugs to treat heart failure

BYETTA slows stomach emptying and can affect medicines that need to pass through the stomach quickly. Ask your doctor or pharmacist if the time at which you take any of your oral medicines (for example, birth control pills, antibiotics) should be changed.

If you must take other medications with food, take them with meals or a snack when you do not also take BYETTA.

Know the medicines you take. Keep a list of them with you to show your doctor or pharmacist each time you get a new medicine.

PROPER USE OF THIS MEDICATION

You should read the Pen User Manual for instructions on how to use the BYETTA Pen and how to inject BYETTA. Pen needles are not included. Ask your doctor or pharmacist which needle length and gauge is best for you.

You must do a "**New Pen Setup**" when starting a new prefilled BYETTA Pen. **Do not repeat a "New Pen Setup" before each injection**, you will run out of medication before 30 days.

Use BYETTA exactly as prescribed by your doctor. Never exceed the prescribed dose.

BYETTA is to be injected under the skin (subcutaneous injection) of your upper leg (thigh), stomach area (abdomen), or upper arm.

If you are using BYETTA and insulin glargine, do not mix the two products together. BYETTA and insulin glargine must be administered as two separate injections in two different injection sites.

BYETTA should be used only if it is clear, colourless and contains no particles. BYETTA should not be transferred from the pen to a syringe or vial.

Do not reuse or share needles with another person as this may risk transmission of infection. BYETTA pens should not be shared with other people.

Usual starting dose: 5 µg twice a day to be injected under the skin at any time within the 60 minute period **before** your morning and evening meals (or before the two main meals of the day, at least 6 hours or more apart). **BYETTA should not be injected after a meal.** The dose of BYETTA may be increased to 10 µg twice daily after a month if required to improve blood sugar control. Maximum is 10 µg twice daily.

Overdose:

If you use too much BYETTA, immediately contact your doctor or regional poison control centre or go to your nearest hospital emergency department. Show the doctor your BYETTA Pen. Too much BYETTA can cause nausea, vomiting, dizziness, or symptoms of low blood sugar.

Missed Dose:

If you miss a dose of BYETTA, DO NOT take an extra dose or increase the amount of your next dose. Skip the dose you missed. Take your next dose at the next prescribed time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects with BYETTA include nausea, vomiting, diarrhea, feeling jittery, dizziness, headache, acid stomach and heartburn.

When BYETTA is used with insulin or a medicine that contains a sulfonylurea, low blood sugar (hypoglycemia) is also common. The dose of your insulin or sulfonylurea medicine may need to be reduced while you use BYETTA. The signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, and feeling jittery. Discuss with your doctor or pharmacist how to treat low blood sugar.

BYETTA may cause new or worsening problems with kidney function, including kidney failure. Dialysis or kidney transplant may be needed. See also **SERIOUS SIDE EFFECTS** table, below.

Injection site reactions (e.g. rash, itching, bruising) have been reported in subjects receiving BYETTA.

Talk to your doctor or pharmacist about any side effect that bothers you or that does not go away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare*	Prolonged severe abdominal pain which may be accompanied by vomiting. These may be symptoms of pancreatitis.			✓
Rare*	Prolonged nausea, vomiting and/or diarrhea, or cannot take liquids by mouth. These may increase the risk of kidney problems.			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your
		Only if severe	In all cases	
Rare*	Sudden swelling of the face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting, very rapid heartbeat. These may be symptoms of angioedema or severe allergic reactions, including anaphylaxis.			✓

*frequency from postmarketing reports

If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations, fainting, or seizures, you should seek immediate medical attention.

This is not a complete list of side effects. For any unexpected effects while taking BYETTA, contact your doctor or pharmacist.

HOW TO STORE IT

- Store your new, unused BYETTA Pen in the original carton in a refrigerator at 2°C to 8°C protected from light. Do not freeze. Throw away any BYETTA Pen that has been frozen.
- After first use, your BYETTA Pen should be stored at 2°C to 25°C.
- Use a BYETTA Pen for only 30 days. Throw away a used BYETTA Pen after 30 days, even if some medicine remains in the pen.
- BYETTA should not be used after the expiration date printed on the label.
- Do not store the BYETTA Pen with the needle attached. If the needle is left on, medicine may leak from the BYETTA Pen or air bubbles may form in the cartridge.
- Keep your BYETTA Pen, pen needles, and all medicines out of the reach of children and pets.
- Throw away used needles in a puncture-resistant container or as recommended by your healthcare professional. Do not throw away the pen with a needle attached. Dispose of pen as directed by your healthcare professional**.**

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **-Fax toll-free to 1-866-678-6789, or**
  - **-Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701D
    Ottawa, ON K1A0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

The most current information, the Consumer Information Leaflet plus the full product monograph, prepared for health professionals can be found at:
www.astrazeneca.ca
or by contacting the sponsor, AstraZeneca Canada Inc. at:
Customer Inquiries 1-800-668-6000,
Renseignements 1-800-461-3787.

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