

BYETTA INJECTION

Exenatide 5mcg & 10mcg

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What BYETTA is used for?

BYETTA is an injectable medicine used to improve blood sugar control in adults with type 2 (non insulin dependent) diabetes mellitus.

How BYETTA works

BYETTA is used with other diabetic medicines called metformin, sulphonylureas or thiazolidinediones. Your doctor is now prescribing BYETTA as an additional medicine to help control your blood sugar. Continue to follow your food and exercise plan.

You have diabetes because your body does not make enough insulin to control the level of sugar in your blood or if your body is not able to use the insulin properly. BYETTA helps your body to increase the production of insulin when your blood sugar is high.

Before you use BYETTA

- When you must not use it

Do not use BYETTA:

- If you are allergic (hypersensitive) to exenatide or any of the other ingredients of BYETTA, listed at the end of this leaflet.

- Before you start to use it

Take special care with BYETTA:

- When using it in combination with a sulphonylurea, as low blood sugar (hypoglycaemia) can occur. Ask your doctor or pharmacist if you are not sure if

any of your other medicines contain a sulphonylurea.

- BYETTA should be injected under the skin and not into a vein or into the muscle.
- If you have severe problems with your stomach emptying (including gastroparesis) or food digestion the use of BYETTA is not recommended. BYETTA slows stomach emptying so food passes more slowly through your stomach.
- The use of BYETTA with insulins is not recommended.
- There is little experience with BYETTA in patients with kidney problems. The use of BYETTA is not recommended if you have severe kidney disease or you are on dialysis.
- 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.

Using BYETTA with food and drink:

Use BYETTA at any time within the 60 minutes (1 hour) **before** your meal. (See "How to use BYETTA"). **Do not** use BYETTA **after** your meal.

Pregnancy and breast-feeding:

It is not known if BYETTA may harm your unborn child. Tell your doctor if you are, you think you might be, or are planning to become pregnant as BYETTA should not be used during pregnancy.

It is not known if BYETTA passes into your milk. BYETTA should not be used if breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

If you use BYETTA in combination with a sulphonylurea, low blood sugar (hypoglycaemia) can occur. Hypoglycaemia may reduce your ability to concentrate. Please keep this possible problem in mind in all situations where you

might put yourself and others at risk (e.g. driving a car or operating machinery).

Important information about some of the ingredients of BYETTA:

This medicine contains less than 1mmol sodium per dose, i.e. essentially "sodium-free". This medicine contains metacresol which may cause allergic reactions.

- Taking other medicines

Using other medicines:

BYETTA slows stomach emptying and can affect medicines that need to pass through the stomach quickly.

Ask your doctor if the time at which you take any tablets (for example, antibiotics) should be changed.

For tablets that you need to take with food, it may be best if they are taken at a meal at a time when BYETTA is not being administered.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to use BYETTA

- How much to use

Always use BYETTA exactly as your doctor or diabetes nurse has told you. You should check with your doctor, diabetes nurse or pharmacist if you are unsure.

Two presentations of BYETTA are available: BYETTA 5 micrograms(μg) and BYETTA 10 micrograms(μg). Your doctor may tell you to use BYETTA 5 μg twice a day to start with. After using BYETTA 5 μg twice a day for 30 days the doctor may increase your dose to BYETTA 10 μg twice a day. One injection of your pre-filled pen will give you your dose. Do not change your dose unless your doctor has told you to.

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- *When to use it*

BYETTA should be injected at any time within the 60 minutes (1 hour) **before** your morning and evening meals, or before your two main meals of the day, which should be about 6 hours or more apart. **Do not** use BYETTA **after** your meal.

- *How long to use it*

If you stop using BYETTA:

If you feel you should stop using BYETTA consult your doctor. If you stop using BYETTA this can affect your blood sugar levels.

- *If you forget to use it*

If you forget to use BYETTA:

If you miss a dose of BYETTA, skip that dose and take your next dose at the next prescribed time. **Do not** take an extra dose or increase the amount of your next dose to make up for the one you missed.

- *If you use too much (overdose)*

If you use more BYETTA than you should:

If you use too much BYETTA you may need medical treatment right away. Too much BYETTA can cause nausea, vomiting, dizziness, or symptoms of low blood sugar.

While you are using it

-*Things you must do*

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

See the accompanying Pen User Manual for instructions for using the BYETTA Pen.

Your doctor or nurse must teach you how to inject BYETTA before you use it for the first time.

Injection needles are not included. The following are examples of disposable needles that can be used with your BYETTA pen:

- 29 (thin), 30 or 31 (thinner) gauge (diameter 0.25 - 0.33mm) and
- 12.7, 8 or 5mm length.

Ask your doctor or nurse, which needle gauge and length is best for you.

Use a new injection needle for each injection and dispose of it after each use.

Read all of this leaflet carefully before you start using this medicine. Keep this leaflet. You may need to read it again.

- *Things you must not do*

This medicine is for you; never share a BYETTA pen with others.

- *Things to be careful of*

You will **not** need to test your sugar levels on a day-by-day basis to set the dose of BYETTA. However, if you are also using a sulphonylurea your doctor may tell you to check your blood sugar levels to adjust the dose of sulphonylurea.

If you have any further questions on the use of this medicine, ask your doctor, diabetes nurse or pharmacist.

Side effects

Like all medicines, BYETTA can have side effects although not everybody gets them.

Very common, more than 1 in 10 patients experienced: nausea, (nausea is most common when first starting BYETTA, but decreases over time in most patients), vomiting or diarrhoea.

When BYETTA is used with a medicine that contains a sulphonylurea, episodes of low blood sugar (hypoglycaemia, generally mild to moderate) can occur very commonly. The dose of your sulphonylurea 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. Your

doctor should tell you how to treat low blood sugar.

Common, less than 1 in 10 but more than 1 in 100 patients experienced: dizziness, headache, reduced appetite, weight decreased, feeling jittery, pain in the stomach area, bloating, indigestion, increased sweating, loss of energy and strength or heartburn, injection site reactions (redness).

In addition some other side effects have been reported: angiodema, hypersensitivity (rashes, itching and rapid swelling of the tissues of the neck, face, mouth or throat), decrease in kidney function, dehydration, sometimes with a decrease in kidney function, unusual taste in the mouth, drowsiness, constipation, burping, flatulence, hair loss (rarely). Changes in INR (measurement of blood thinning) have been reported when used together with warfarin.

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving BYETTA. Pancreatitis can be a serious, potentially life-threatening medical condition.

- Tell your doctor if you have had pancreatitis, gallstones, alcoholism or very high triglycerides.
- These medical conditions can increase your chance of getting pancreatitis, or getting it again, whether or not you are taking BYETTA.
- Call your doctor if you experience **severe and persistent** stomach pain, with or without vomiting, because you could have pancreatitis.

Some severe allergic reactions (anaphylaxis) have been reported very rarely.

You should see your doctor immediately if you experience symptoms such as

- Swollen face, tongue or throat
- Difficulty to swallow
- Hives and difficulties to breathe

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BYETTA may reduce your appetite, the amount of food you eat, and your weight.

Take care if you lose weight too quickly as this may not be good for you (for example, it can cause dehydration, dizziness upon standing, and gallstones).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling TEL: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of BYETTA

Storage

Keep out of the reach and sight of children.

Do not use BYETTA after the expiry date, which is stated on the label and the carton.

Store in a refrigerator (2 °C - 8 °C). After first use, your BYETTA pen should be refrigerated or kept cold 2° to 8°C when not in use. However, the medicine is stable up to 25°C for 7 days (168 hours), during the 30 day in use period.

Replace the cap on the pen in order to protect from light. Do not freeze. Throw away any BYETTA pen that has been frozen.

Use a BYETTA pen for only 30 days. Dispose of a used BYETTA pen after 30 days, even if some medicine remains in the pen.

Do not use BYETTA if you notice particles in the solution, or if it is cloudy or coloured.

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.

Disposal

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

BYETTA is a clear and colourless liquid (solution for injection) filled in a glass cartridge within a pen. When the pen is empty, you cannot use it again. Each pen has 60 doses to provide 30 days of twice-a-day injections.

Two pre-filled pens are available one to deliver doses of 5 micrograms (µg) and one 10 micrograms (µg).

Each dose of BYETTA 5 micrograms solution for injection contains 5 micrograms exenatide in 20 microlitre.

Each dose of BYETTA 10 micrograms solution for injection contains 10 micrograms exenatide in 40 microlitre.

Each millilitre (ml) of the solution for injection contains 0.25 milligrams (mg) of exenatide.

It is available in pack sizes of 1 and 3 pens. Not all pack sizes may be marketed.

- Ingredients

Active ingredient: exenatide.

Inactive ingredients: metacresol (44 micrograms/dose in BYETTA 5 micrograms solution for injection and 88 micrograms/dose in BYETTA 10 micrograms solution for injection), mannitol, glacial acetic acid, sodium acetate trihydrate and water for injections.

- MAL number

BYETTA 5 micrograms solution for injection, pre-filled pen (MAL09051565ACS)
BYETTA 10 micrograms solution for injection, pre-filled pen (MAL09051566ACS)

Manufacturer

Baxter Pharmaceutical Solutions LLC
927 South Curry Pike,
Bloomington, Indiana 47403,
USA.

Product Registration Holder

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