

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Byetta 5 micrograms solution for injection, pre-filled pen Byetta 10 micrograms solution for injection, pre-filled pen exenatide**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or diabetes nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist, or diabetes nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Byetta is and what it is used for
2. What you need to know before you use Byetta
3. How to use Byetta
4. Possible side effects
5. How to store Byetta
6. Contents of the pack and other information

#### **1. What Byetta is and what it is used for**

Byetta contains the active substance exenatide. It is an injectable medicine used to improve blood sugar control in adults with type 2 (non insulin dependent) diabetes mellitus.

Byetta is used with other diabetic medicines called metformin, sulphonylureas, thiazolidinediones and basal or long acting insulins. 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. The medicine in Byetta helps your body to increase the production of insulin when your blood sugar is high.

#### **2. What you need to know before you use Byetta**

##### **Do not use Byetta**

- If you are allergic to exenatide or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor, pharmacist, or diabetes nurse before using Byetta about the following:

- When using Byetta in combination with a sulphonylurea, as low blood sugar (hypoglycaemia) can occur. Ask your doctor, pharmacist, or diabetes nurse if you are not sure if any of your other medicines contain a sulphonylurea.
- Byetta should not be used if you have type 1 diabetes or diabetic ketoacidosis (a dangerous condition that can occur in diabetes).
- 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.
- Tell your doctor if you have ever had inflammation of the pancreas (pancreatitis) (see section 4).
- There is little experience with Byetta in patients with a BMI (body mass index)  $\leq 25$ .
- 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.

### **Children and adolescents**

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.

### **Other medicines and Byetta**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Ask your doctor if the time at which you take any tablets should be changed because Byetta slows stomach emptying and can affect medicines that need to pass through the stomach quickly.

Stomach resistant tablets or capsules (for example proton pump inhibitors) that should not stay too long in your stomach may need to be taken an hour before, or four hours after Byetta.

Some antibiotics may need to be taken an hour before your Byetta injection.

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.

The use of Byetta with other medicines that are used to treat type 2 diabetes that work like Byetta (for example: liraglutide and Bydureon [exenatide once weekly]), is not recommended.

### **Byetta with food and drink**

Use Byetta at any time within the 60 minutes (1 hour) **before** your meal. (See 3 “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. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advise before taking this medicine, as Byetta should not be used during pregnancy.

It is not known if the medicine in Byetta passes into your milk. Byetta should not be used if breast-feeding.

### **Driving and using machines**

If you use Byetta in combination with a sulphonylurea or insulin, 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 using machines).

**Byetta contains metacresol**

Metacresol may cause allergic reactions.

**Byetta contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium-free”.

**3. How to use Byetta**

Always use this medicine exactly as your doctor, pharmacist, or diabetes nurse has told you. Check with your doctor, pharmacist, or diabetes nurse if you are not sure.

Two strengths of Byetta are available: Byetta 5 micrograms and Byetta 10 micrograms. Your doctor may tell you to use Byetta 5 micrograms twice a day to start with. After using Byetta 5 micrograms twice a day for 30 days the doctor may increase your dose to Byetta 10 micrograms twice a day.

If you are over 70 years old or have problems with your kidneys it may take longer than 30 days to tolerate the Byetta 5 micrograms dose and so your doctor may not increase your dose.

One injection of your pre-filled pen will give you your dose. Do not change your dose unless your doctor has told you to.

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.

Byetta is injected under the skin (subcutaneous injection) of your upper leg (thigh), stomach area (abdomen), or upper arm. If you are using Byetta and an insulin you must make two separate injections.

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 or an insulin your doctor may tell you to check your blood sugar levels to adjust the dose of sulphonylurea or insulin.

**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.

Becton, Dickinson and Company needles are suitable to use with the Byetta pen. Injection needles are not included.

Use a new injection needle for each injection and dispose of it after each use. This medicine is for you; never share a Byetta pen with others.

**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 (see section 4).

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Severe allergic reactions** (anaphylaxis) have been reported very rarely (may affect up to 1 in 10,000 people).

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

**Cases of inflammation of the pancreas** (pancreatitis) have been reported rarely (may affect up to 1 in 1,000 people) 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.
- STOP taking Byetta and contact your doctor immediately if you experience **severe and persistent** stomach pain, with or without vomiting, because you could have an inflamed pancreas (pancreatitis).

**Very common** side effects of Byetta (may affect more than 1 in 10 people):

- nausea, (nausea is most common when first starting Byetta, but decreases over time in most patients)
- vomiting
- diarrhoea
- hypoglycaemia

When Byetta is used with a medicine that contains a **sulphonylurea or an insulin**, episodes of low blood sugar (hypoglycaemia, generally mild to moderate) can occur very commonly. The dose of your sulphonylurea or insulin 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** side effects of Byetta (may affect up to 1 in 10 people):

- dizziness
- headache
- feeling jittery
- pain in the stomach area
- bloating
- indigestion
- increased sweating

- loss of energy and strength
- heartburn
- injection site reactions (redness)
- weight decreased
- reduced appetite

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

If you lose weight too quickly (more than 1.5 kg per week) talk to your doctor about it since this may not be good for you.

**Uncommon** side effects of Byetta (may affect up to 1 in 100 people):

- unusual taste in the mouth
- burping
- constipation
- gas (flatulence)

**Rare** side effects of Byetta:

- intestinal obstruction (blockage in intestine)
- angioedema (swelling of the face and throat)
- 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
- drowsiness
- hair loss

In addition some **other side effects** have been reported (frequency not known, cannot be estimated from the available data).

- Changes in INR (measurement of blood thinning) have been reported when used together with warfarin.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or diabetes nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

### **Ireland**

HPRA Pharmacovigilance

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Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

### **Malta**

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

## 5. How to store Byetta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Once in use, your Byetta pen should be kept below 25°C for 30 days.

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.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Byetta contains

- The active substance is exenatide.
- Two pre-filled pens are available. One to deliver doses of 5 micrograms and one 10 micrograms.
- Each dose of Byetta 5 micrograms solution for injection (injection) contains 5 micrograms exenatide in 20 microlitre.
- Each dose of Byetta 10 micrograms solution for injection (injection) contains 10 micrograms exenatide in 40 microlitre.
- Each millilitre (ml) of the solution for injection contains 0.25 milligrams (mg) of exenatide.
- The other ingredients are 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.

### What Byetta looks like and contents of the pack

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.

Byetta is available in pack sizes of 1 and 3 pre-filled pens. Not all pack sizes may be marketed.

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*This leaflet was last approved in 02/2015*

Detailed information on this medicine is available on the website of the European Medicines Agency  
<http://www.ema.europa.eu/>

CV 15 0059