

Package leaflet: Information for the patient

Byetta® 5 micrograms solution for injection in 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.

The name of your medicine is Byetta 5 micrograms solution for injection in pre-filled pen but will be referred to as Byetta throughout this leaflet. Please note that this leaflet also contains information about other strength Byetta 10 micrograms solution for injection in pre-filled pen.

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:

- Using this medicine 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.
- If you have type 1 diabetes or diabetic ketoacidosis (a dangerous condition that can occur in diabetes), as you should not use this medicine.
- How to inject this medicine. It should be injected under the skin and not into a vein or into the muscle.
- If you have severe problems with slow stomach emptying or food digestion, as the use of this medicine is not recommended. The active substance in this medicine slows stomach emptying so food passes more slowly through your stomach.
- If you have ever had inflammation of the pancreas (pancreatitis) (see section 4).
- If you lose weight too quickly (more than 1.5kg per week) talk to your doctor about it since this may cause problems such as gallstones.
- If you have severe kidney disease or you are on dialysis, as the use of this medicine is not recommended. There is little experience with this medicine in patients with kidney problems.

Byetta is not an insulin and should therefore not be used as a substitute for insulin.

Children and adolescents

Do not give this medicine to children and adolescents less than 18 years as there is no experience with this medicine 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, particularly:

- medicines that are used to treat type 2 diabetes that work like Byetta (e.g. liraglutide and prolonged-release exenatide), as taking these medicines with Byetta is not recommended.
- medicines used to thin the blood (anticoagulants), e.g. warfarin, as you will require additional monitoring of changes in INR (measurement of blood thinning) during initiation of therapy with this medicine.

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

- Stomach resistant tablets or capsules (e.g. medicines that reduce stomach acid (proton pump inhibitors)) that should not stay too long in your stomach, may need to be taken an hour before, or four hours after this medicine.
- 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 this medicine is not being administered.

Byetta with food

Use this medicine at any time within the 60 minutes (1 hour) **before** your meal. (See section 3 'How to use Byetta'). **Do not** use this medicine **after** your meal.

Pregnancy and breast-feeding

It is not known if this medicine may harm your unborn child. If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as it should not be used during pregnancy.

It is not known if exenatide passes into your milk. This medicine should not be used if breast-feeding.

Driving and using machines

If you use this medicine 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 1mmol sodium (23mg) 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.

You should inject this medicine 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 this medicine **after** your meal.

You should inject this medicine 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. If you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend that you monitor your blood sugar more frequently, in order to avoid hyperglycaemia (high blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough 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 more of this medicine than you should, talk to a doctor or go to a hospital right away. Using too much of this medicine 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 this medicine, skip that dose and use your next dose at the next prescribed time. **Do not** use 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 this medicine consult your doctor first. If you stop using this medicine 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 rarely (may affect up to 1 in 1,000 people).

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

- Swelling of the face, tongue or throat (angioedema)
- Rashes, itching and rapid swelling of the tissues of the neck, face, mouth or throat
- Difficulty to swallow
- Hives and difficulties to breathe

Cases of inflammation of the pancreas (pancreatitis) have been reported (frequency not known) in patients receiving this medicine. 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 this medicine.
- STOP taking this medicine 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 (may affect more than 1 in 10 people):

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

When this medicine 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 this medicine. 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 (may affect up to 1 in 10 people):

- dizziness
- headache
- feeling jittery
- constipation
- pain in the stomach area
- bloating
- indigestion
- itching (with or without rash)
- flatulence (passing gas)
- increased sweating
- loss of energy and strength
- heartburn
- reduced appetite

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

If you lose weight too quickly (more than 1.5kg per week) talk to your doctor about it since this may cause problems such as gallstones.

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

- decreased in kidney function
- dehydration, generally associated with nausea, vomiting and/or diarrhoea
- unusual taste in the mouth
- burping
- injection site reactions (redness)
- sleepiness
- hair loss
- weight decreased
- a delay in the emptying of the stomach
- inflamed gallbladder
- gallstones

Rare side effects (may affect up to 1 in 1,000 people):

- intestinal obstruction (blockage in intestine)

Not known (frequency cannot be estimated from the available data).

In addition some **other side effects** have been reported:

- bleeding or bruising more easily than normal due to low level of blood platelets.
- 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 via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Byetta

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Once in use, keep your pen below 25°C for 30 days. Dispose of a used pen after 30 days, even if some medicine remains in the pen.

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

Do not store the pen with the needle attached. If the needle is left on, medicine may leak from the pen or air bubbles may form in the cartridge.

Do not use the injection after the expiry date, which is stated on the carton and pen labels after 'Exp'. The expiry date refers to the last day of that month.

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

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

6. Contents of the pack and other information

What Byetta contains

The active ingredient in the Byetta is exenatide.

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

Each ml of the solution contains 0.25mg exenatide for injection.

The other ingredients are metacresol, (44 micrograms/dose in Byetta 5 micrograms solution for injection), mannitol, glacial acetic acid, sodium acetate trihydrate and water for injections (see section 2).

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.

It is available in pack sizes of 1 and 3 pre-filled pens.

Manufacturer and Product Licence Holder

Manufactured by:

AstraZeneca AB, Global External Sourcing (GES), Astraallen, Gartunaporten (B 674:5), SE-151 85 Sodertalje, Sweden.

Procured from within the EU by Product Licence holder: Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD.Repackaged by Servipharm Ltd.

Byetta® 5 micrograms solution for injection in pre-filled pen; PL 20636/3555

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POM

Byetta is the registered trademark of AstraZeneca Pharmaceuticals LP.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call **020 8423 2111** to obtain the leaflet in a format suitable for you.

PEN USER MANUAL

Byetta® 5 micrograms solution for injection in pre-filled pen (exenatide)



USER MANUAL CONTENTS

Section 1 – WHAT YOU NEED TO KNOW ABOUT YOUR BYETTA PEN

Section 2 – GETTING STARTED: FOR FIRST TIME USERS OR NEW PENS

Section 3 – ROUTINE USE: FOR PEOPLE WHO HAVE SET UP THEIR PEN

Section 4 – COMMONLY ASKED QUESTIONS: FOR QUESTIONS RELATED TO THE PEN

Section 1. WHAT YOU NEED TO KNOW ABOUT YOUR BYETTA PEN

Read this section completely before you begin. Then, move on to section 2 – getting started.

Read these instructions carefully BEFORE using your Byetta pen. Also read the Byetta Package leaflet that comes with the Byetta pen carton.

You need to use the pen correctly in order to get the most benefit from Byetta. Failure to follow these instructions completely may result in a wrong dose, a broken pen or an infection.

These instructions do not take the place of talking with your healthcare professional about your medical condition or your treatment. If you are having problems using your Byetta pen, contact your healthcare professional.

IMPORTANT INFORMATION ABOUT YOUR BYETTA PEN

- Byetta is injected twice a day, the pen contains enough medicine for 30 days. You do not have to measure any doses, the pen measures each dose for you.
- **DO NOT TRANSFER THE MEDICINE IN THE BYETTA PEN TO A SYRINGE.**
- If any part of your pen appears broken or damaged, do not use the pen.
- **Do not share your pen or needles as this may risk transmission of infectious agents.**
- This pen is not recommended for use by people who are blind or who cannot see well enough. Help will be needed by a person trained to use the pen.
- Healthcare professionals or other caregivers should follow local or institutional policies regarding needle handling.
- **Follow the instructions for hygienic injection technique recommended by your healthcare professional.**

- Follow Section 2 only to set up a new pen before first use.
- Section 3 of this manual should be used for every injection.

ABOUT INJECTION NEEDLES

Your Byetta pen is suitable for use with Becton, Dickinson and Company pen injection needles.

Do I use a new needle for each injection?

- Yes. Do not reuse needles.
- Remove the needle immediately after each injection. This will help prevent leakage of Byetta, keep out air bubbles, reduce needle clogs, and decrease the risk of infection.
- Never push the injection button on the pen unless a needle is attached.

How do I throw away my needles?

- 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.

STORING YOUR BYETTA PEN

How do I store my Byetta pen?

- Store in a refrigerator (2°C to 8°C).
- Do not freeze. Throw away any Byetta pen that has been frozen.
- Once in use, your Byetta pen should be kept below 25°C.
- Replace the cap on the pen in order to protect from light.
- 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 pen and needles out of the sight and reach of children.

How long can I use a Byetta pen?

- Use a Byetta pen for only 30 days after setting up a new pen for first use.
- **Dispose of a used Byetta pen after 30 days, even if some medicine remains in the pen.**
- Mark the date when you first used your pen and the date 30 days later in the spaces below:

Date of first use _____ Date to throw away pen _____

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

How do I clean my Byetta pen?

- If needed, wipe the outside of the pen with a clean, damp cloth.
- White particles may appear on the outside tip of the cartridge during normal use. You may remove them with an alcohol wipe or alcohol swab.

Please see the accompanying Byetta Package Leaflet. For additional information, contact your healthcare professional.

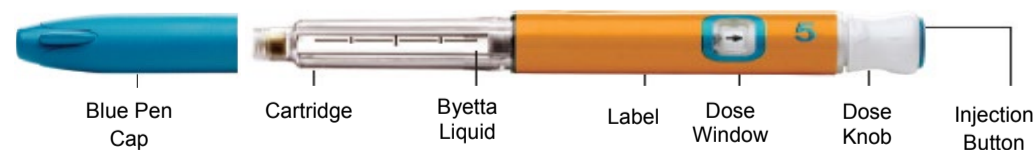
Section 2.

GETTING STARTED

Read and follow the directions in this section only after you've read section 1-what you need to know about your Byetta pen.

Set up your new pen just before you use it for the first time. Follow the **New Pen Setup** only **once**. For routine use, **do not repeat** the New Pen Setup. If you do, you will run out of Byetta before 30 days of use.

BYETTA PEN PARTS



Blue Pen Cap

Cartridge

Byetta Liquid

Label

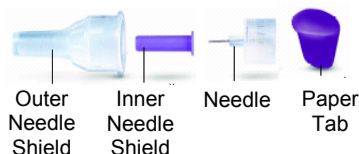
Dose Window

Dose Knob

Injection Button

NEEDLE PARTS

(Needles Not Included)



Outer Needle Shield

Inner Needle Shield

Needle

Paper Tab

DOSE WINDOW SYMBOLS

- ➡ ready to pull dose knob out
- ⬆ ready to turn to dose position
- 5 ready to inject 5 micrograms (mcg)
- ▲ dose knob pushed in and ready to reset

NEW PEN SETUP – DO THIS ONE TIME ONLY

STEP A Check the Pen



- Wash hands prior to use.
- Check pen label to make sure it is your 5 microgram pen.
- Pull off the blue pen cap.



Check Byetta in the cartridge. The liquid should be clear, colourless, and free of particles. If it is not, do not use.

Note: A small air bubble in the cartridge is normal

STEP B Attach the Needle



- Remove paper tab from outer needle shield.
- **Push** outer needle shield containing the needle **straight** onto the pen, then **screw** needle on until secure.



- Pull off outer needle shield. **Do not** throw away. The outer needle shield will be used when you are removing the needle from the pen after the injection.



- Pull off inner needle shield and throw away. A small drop of liquid may appear. This is normal.

STEP C Dial the Dose



- Check that the ➡ is in the dose window. If not, turn dose knob clockwise **until it stops** and the ➡ is in the dose window.



- Pull dose knob out until it stops and the ⬆ is in the dose window.



- Turn dose knob clockwise until it stops at 5. Make sure that the 5 with the line under it is in the centre of the dose window.

Note: If you cannot turn the dose knob clockwise to the 5, see **Commonly Asked Questions**, number 9, in Section 4 of this user manual.

STEP D Prepare the pen



- Point the needle of the pen up and away from you.



PUSH & HOLD

- Use thumb to firmly push the injection button in until it stops, then continue holding the injection button in while **slowly counting to 5**.
- **If you do not see a stream or several drops come from the needle tip, repeat Steps C & D.**



- Pen preparation is complete when the ▲ is in the centre of the dose window AND you have seen a stream or several drops come from the needle tip.

Note: If you do not see liquid after 4 times, see **Commonly Asked Questions**, number 3, in Section 4 of this user manual.

STEP E Complete New Pen Setup



- Turn dose knob clockwise until it stops and the ➡ is in the dose window.

- New Pen Setup is now done. Do not repeat Section 2 for routine use, if you do, you will run out of Byetta before 30 days of use.

- You are now ready for your first dose of Byetta.
- **Go to Section 3, Step 3, for instructions on how to inject your first routine dose.**

Note: If you cannot turn the dose knob, see **Commonly Asked Questions**, number 9, Section 4 of this user manual.

Section 3.

ROUTINE USE

Now that you have done the New Pen Setup, follow Section 3 for **all** of your injections.

STEP 1 Check the Pen



- Wash hands prior to use.
- Check pen label to make sure it is your 5 microgram pen.
- Pull off the blue pen cap.



- Check Byetta in the cartridge.
- The liquid should be clear, colourless, and free of particles. If it is not, do not use.

Note: A small air bubble will not harm you or affect your dose.

STEP 2 Attach the Needle



- Remove paper tab from outer needle shield.
- **Push** outer needle shield containing the needle **straight** onto the pen, then **screw** needle on until secure.



- Pull off outer needle shield. **Do not** throw away. The outer needle shield will be used when you are removing the needle from the pen after the injection.





- Pull off inner needle shield and throw away. A small drop of liquid may appear. This is normal.


Note: If the needle is not secure, you may not get your full dose.

STEP 3 Dial the Dose





- Check that the  is in the dose window. If not, turn dose knob clockwise **until it stops** and the  is in the dose window.



- **Pull dose knob out until it stops** and the  is in the dose window.



- **Turn dose knob clockwise until it stops** at . Make sure that the 5 with the line under it is in the centre of the dose window.

Note: If you cannot turn the dose knob clockwise to the , see **Commonly Asked Questions**, number 9, in Section 4 of this user manual.

STEP 4 Inject the Dose

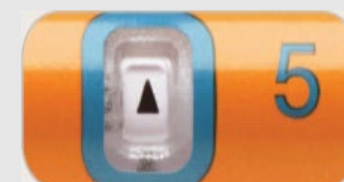



- Grip pen firmly.
- Avoid tightly pinching the skin before injecting. Insert needle into skin using **hygienic** injection technique recommended by your healthcare professional.



PUSH & HOLD

- **Use thumb to firmly push injection button in until it stops**, then continue holding the injection button in while **slowly counting to 5** in order to get a full dose.
- Keep the pressure on the injection button as you remove the needle from your skin, this keeps the medication in the cartridge clear. See **Commonly Asked Question 4**.




- Injection is complete when the  is in the centre of the dose window.
- The pen is now ready to reset.

Note: If you see several drops of Byetta leaking from the needle after the injection, the injection button was not pushed in all the way. See **Commonly Asked Questions**, number 5, in Section 4 of this user manual.

STEP 5 Reset the Pen



- **Turn dose knob clockwise until it stops** and the  is in the dose window.

Note: If you cannot turn the dose knob, or if your pen leaks, your full dose has not been delivered. See **Commonly Asked Questions**, numbers 5 and 9, in Section 4 of this user manual.

Note: This needs to be done after each injection.

STEP 6 Remove and Dispose of the Needle



- Carefully put the outer needle shield back over the needle.
- **Remove the needle after each injection.** This prevents the liquid from leaking out.



- Unscrew the needle.
- Replace blue pen cap on pen before storage.



- Throw away needles in a puncture-resistant container or as recommended by your healthcare professional.

STEP 7 Store pen for next dose

- Store your Byetta pen properly. (See **'Storing Your Byetta Pen'** in Section 1 of this user manual for more information.)
- When it is time for your next routine dose, go to **Section 3, Step 1**, and repeat Steps 1 - 7.

Section 4. COMMONLY ASKED QUESTIONS

1. Do I need to do the New Pen Setup before every dose?

- No. The New Pen Setup is done only **once**, just before each new pen is used for the first time.
- The purpose of the setup is to make sure that your Byetta pen is ready to use for the next 30 days.
- **If you repeat the New Pen Setup before each routine dose, you will not have enough Byetta for 30 days.** The small amount of Byetta used in the New Pen Setup will not affect the 30-day supply of Byetta.

2. Why are there air bubbles in the cartridge?

- A small air bubble is normal. It will not harm you or affect your dose.
- If the pen is stored with a needle attached, air bubbles may form in the cartridge. **Do not** store the pen with the needle attached.

3. What should I do if Byetta does not come out of the needle tip after four tries during New Pen Setup?

- Remove the needle by carefully putting the outer needle shield back over the needle. Unscrew and dispose of properly.
- Attach a new needle and repeat **New Pen Setup, Steps B – E**, in Section 2 of this user manual. Once you see several drops or a stream of liquid coming out of the tip of the needle, the setup is complete.




4. Why do I see particles in the cartridge after I finish my injection?

Particles or discoloration may appear in the cartridge after an injection. This may happen if the skin is pinched too tightly or if the pressure on the injection button is released before the needle is removed from the skin.

5. Why do I see Byetta leaking from my needle after I have finished my injection?


- It is normal for a single drop to remain on the tip of your needle after your injection is complete. If you see more than one drop:
 - You may not have received your full dose. **Do not** inject another dose. **Consult with your healthcare professional about how to handle a partial dose.**
 - To prevent this, for your next dose, **firmly push and hold** the injection button in and **slowly count to 5** (see **Section 3, Step 4: Inject the Dose**).

6. What do the arrows mean?

The arrows mean you are ready for the next step. These arrows   show the direction to pull or turn the dose knob in the next step. This symbol  means the dose knob is pushed in and the pen is ready to reset.

7. How can I tell when the injection is complete?

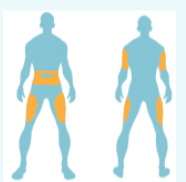
The injection is complete when:

- You have firmly pushed the injection button in all the way **until it stops** and
- You have **slowly counted to 5** while you are still holding the injection button in and the needle is still in your skin and
- The  is in the centre of the dose window.

8. Where should I inject Byetta?

Byetta should be injected into your abdomen, thigh, or upper arm using the injection technique recommended by your healthcare professional.


Front Back



9. What if I cannot pull, turn, or push the dose knob?

Check the symbol in the dose window. Follow the steps next to the matching symbol.


If is in the dose window:

- Pull the dose knob out until  appears.

If is in the dose window and the dose knob will not turn:

- The cartridge in your Byetta pen may not have enough liquid to deliver a full dose. A small amount of Byetta will always remain in the cartridge. If the cartridge contains a small amount or looks empty, obtain a new Byetta pen.


If and part of the are in the dose window and the dose knob cannot be pushed in:

- The dose knob was not turned all the way. Continue turning the dose knob clockwise until  is in the centre of the dose window.

If part of and part of are in the dose window and the dose knob cannot be pushed in:

- The needle may be clogged, bent, or incorrectly attached.
- Attach a new needle. Make sure needle is on straight and screwed on all the way.
- Firmly push the injection button in all the way. Byetta should come from needle tip.

If is in the dose window and the dose knob will not turn:

- The injection button was not pushed in all the way and a complete dose was not delivered. **Consult with your healthcare professional about how to handle a partial dose.**
- Follow these steps to reset your pen for your next injection:
 - Firmly push the injection button in all the way **until it stops**. Keep holding the injection button in and **slowly count to 5**. Then turn the dose knob clockwise until  appears in the dose window.
 - If you cannot turn the dose knob, the needle may be clogged. Replace the needle and repeat the step above.
- For your next dose, be sure to **firmly push and hold** the injection button in and **slowly count to 5** before removing needle from skin.

Please see the accompanying Package Leaflet. For additional information contact your healthcare professional.

Byetta® 5 micrograms solution for injection in pre-filled pen; PL 20636/3555

Leaflet Date: 13.03.25[1-UM]