Byetta®

Exenatide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BYETTA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about BYETTA and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BYETTA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, consult your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What BYETTA is used for

BYETTA is an injectable medicine used to improve blood sugar control in adults with type 2 diabetes mellitus. It is used with metformin or a sulfonylurea. It may also be used with a combination of both metformin and a sulfonylurea.

Ask your doctor or healthcare professional if you are not sure whether your antidiabetic medicine contains a sulfonylurea.

Diabetes mellitus is a condition in which your pancreas does not produce enough insulin to control your blood sugar level. BYETTA helps your body to increase production of insulin when your blood sugar is high.

BYETTA is not a substitute for insulin in patients who require insulin treatments for their diabetes.

This medicine has not been studied in children.

This medicine is only available with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use BYETTA

When you must not use it

Do not use BYETTA if:

- you have type 1 diabetes or diabetic ketoacidosis (often caused by very high blood glucose levels).
- you are allergic to exenatide or meta-Cresol or any of the ingredients listed at the end of this leaflet
- you have severe kidney problems or you are on dialysis.

Do not use BYETTA after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Return the product to your pharmacist if it has expired or is damaged.

Do not use BYETTA if you see solid particles or if the solution is cloudy or coloured.

Talk to your doctor if you are not sure whether you should start using BYETTA.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- high blood pressure or other heart problems
- high cholesterol and triglycerides (a lipid disorder involving too many fatty acids in the blood stream)
- pancreatitis
- gall stones
- inflammation of the gall bladder (cholecystitis)
- alcohol abuse.

Tell your doctor if you have severe problems with your stomach or food digestion.

BYETTA slows stomach emptying so food passes more slowly through your stomach.

Tell your doctor if you are pregnant or plan to become pregnant.

Use of this medicine in pregnancy is limited. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is not known if this medicine passes into your breast milk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start using this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by BYETTA or may affect how it works. You may need different amounts of your medicines or you may need to take different medicines.

These include:

- medicines that need to pass through the stomach quickly. BYETTA slows stomach emptying and can affect these medicines
- other medicines used to control your blood sugar levels
- orlistat, a weight loss medicine
- opioids, a narcotic commonly used as a pain killer
- biphosphonates, a type of medicine used to treat osteoporosis
- anticholinergics, a type of medicine used to relieve stomach cramps or spasms, to treat travel sickness and to treat Parkinson's disease
- statins, a type of medicine used to lower cholesterol
- oral contraceptives or oral antibiotics.

You can still take the following medicines while you are taking BYETTA. However, you must take the following medicines at least 1 hour before BYETTA.

- proton pump inhibitors, a type of medicine to treat stomach ulcers or acid in your stomach.

You can still take the following medicines while you are taking BYETTA. However you must take the following medicines at least 1 hour before or at least 4 hours after taking BYETTA.

- warfarin, a medicine used to prevent blood clots. Taking BYETTA while you are taking warfarin may cause you to bleed more easily
- angiotensin converting enzyme inhibitors, medicines used to treat high blood pressure and other heart conditions
- nonsteroidal anti-inflammatory medicines
- diuretics, medicines used to treat fluid retention and high blood pressure. Taking BYETTA while you are taking these medicines may affect your kidneys.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use BYETTA

Carefully follow all the directions given to you by your doctor or health care professional.

They may differ from the information contained in this leaflet.

Ask your doctor or healthcare professional which needle length and gauge is best for you.

Needles are not included with the pen.

How to use it

BYETTA is given by injection under the skin (subcutaneous) into the thigh, abdomen or upper arms.

BYETTA comes in a pre-filled pen with fixed dosing. Your health care professional should teach you how to use the BYETTA pen.

Read the User Manual for information on how to use the pen before beginning therapy.

Read the User Manual each time you get a new pen, in case something has changed.

Refer to the User Manual each time you inject this medicine.

If you do not understand the User Manual, ask your doctor or health care professional for help.

How much to use

BYETTA is available as a 5 microgram dose and as a 10 microgram dose. It is usual for your doctor to start your BYETTA therapy with the lower dose.

Use BYETTA exactly as prescribed by your doctor.

Your doctor will tell you how much of this medicine you need to use each day. Any change in dose should be made cautiously and only under medical supervision.

When to use it

Inject BYETTA twice a day, within 60 minutes (1 hour) before your morning and evening meals (or two main meals of the day, approximately 6 hours or more apart).

Do not take BYETTA after your meal.

How long to use it

Do not stop using BYETTA unless your doctor tells you to.

If you forget to use it

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.

Ask your healthcare professional if you are not sure what to do.

If you have trouble remembering to use your medicine, ask your doctor or healthcare professional for some hints.

If you take too much (overdose)

If you take too much BYETTA, immediately call your doctor or the Poisons Information Centre (telephone Aust: 131126, NZ: 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital.

Symptoms of an overdose may include nausea, vomiting, dizziness, or symptoms of low blood sugar. You may need urgent medical attention.

While you are using BYETTA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using BYETTA.

Tell any other doctors, dentists and health care professionals who treat you that you are using this medication.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

Tell your doctor if you experience hypoglycaemia (low blood sugar levels).

When BYETTA is used with a medicine that contains a sulfonylurea, hypoglycaemia can occur. The dose of your sulfonylurea medicine may need to be reduced while you use BYETTA.

Some symptoms of hypoglycaemia are:

- drowsiness
- weakness
- confusion
- irritability
- hunger
- fast heartbeat
- sweating.

If you are experiencing any of these symptoms of hypoglycaemia, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypoglycaemia.

Under certain conditions, the early warning signs of hypoglycaemia can be different or less obvious.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

You may not be able to get BYETTA in the country you are visiting.

Ask your doctor for a letter explaining why you are taking injecting devices with you.

Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your BYETTA and eat your meals at different times because of time differences in and between countries.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

Things you must not do

Do not stop using your medicine or change your dosage unless your doctor tells you to.

Do not use the medicine if you think it has been frozen or exposed to excessive heat.

It will not work as it should.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia, or make it worse.

Be careful driving or operating machinery.

If you use BYETTA in combination with a sulfonylurea, hypoglycaemia can occur. Hypoglycaemia may reduce your ability to concentrate.

Side effects

Tell your doctor or healthcare professional as soon as possible if you do not feel well while you are using BYETTA.

BYETTA helps most people with type 2 diabetes, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or healthcare professional to answer any questions you may have.

When BYETTA is used with a medicine that contains a sulfonylurea, hypoglycaemia can occur.

Tell your doctor if you experience hypoglycaemia.

Tell your doctor if you notice any of the following:

- nausea
- vomiting
- diarrhoea
- dizziness or light headedness
- headache
- feeling jittery
- acid stomach
- abdominal pain or distension
- loss of energy and strength
- redness, swelling or itching at the injection site (local allergy)
- indigestion (dyspepsia)
- excessive sweating (hyperhidrosis)
- hair loss.

These are the more common side effects of BYETTA. Mostly these are mild and short-lived.

When using BYETTA some patients have lost >1.5 kg of weight per week.

Tell your doctor if you experience rapid weight loss.

Not all patients will lose weight. BYETTA may reduce your appetite. Nausea and vomiting were very commonly reported in patients using BYETTA. Mostly these were mild to moderate and short-lived. In most patients who initially experienced nausea, the frequency and severity decreased with continued therapy.

You may experience dehydration as a result of nausea, vomiting and/or diarrhoea. Some symptoms of mild to moderate dehydration are:

- dry mouth
- decreased frequency of urination and concentrated urine
- headache
- muscle weakness
- dizziness or light headedness.

Drink plenty of fluids if you are experiencing any of these symptoms. Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you continue to experience these symptoms.

Tell your doctor immediately if you notice any of the following:

- passing little or no urine
- taste disturbance or loss of taste
- sleepiness or drowsiness
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- stomach discomfort relieved by belching or passing wind
- constipation
- itching
- hives, pinkish, itchy swellings on the skin, itchy rash
- red raised skin rash
- bleeding more easily than normal, if you are taking warfarin.

These are rare or very rare side effects of BYETTA. The above list includes serious side effects which may require medical attention.

Tell your doctor immediately if you are experiencing any of the following:

- severe abdominal pain and
- vomiting and/or
- diarrhoea and/or
- nausea.

These can be symptoms of acute pancreatitis which has been reported rarely in patients taking BYETTA.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using BYETTA

Storage

Keep your BYETTA pen in the refrigerator where the temperature stays between 2 - 8 ºC. Do not freeze. Do not use BYETTA if it has been frozen.

You may keep your BYETTA pen below 25 ºC for up to 30 days while you are using the pen. Do not put your BYETTA pen near heat or in the sun.

Keep this medicine where children cannot reach it.

Remove the needle and put the pen back into the refrigerator immediately after you have used it.

Use a new needle for each injection.

Do not store your pen with the needle attached.

If you do this, it may allow solution to leak from the pen and air bubbles to form in the cartridge.

Each BYETTA pen can be used for up to 30 days after the first injection.

Discard the pen after 30 days, even if it contains some unused solution.

Ask your pharmacist how to discard the pen.

The BYETTA pen is for use in a single patient only.

Disposal

Dispose of your needles and pen safely into a yellow plastic sharps container or similar puncture proof container composed of hard plastic or glass.

Ask your doctor, nurse or pharmacist where you can dispose of the container when it is full.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

BYETTA is a clear colourless liquid. It is supplied in a 5 microgram or 10 microgram pre-filled delivery device (pen). Each pen contains dosing for 30 treatment days.

BYETTA is available in packs of 1 pen.

Ingredients

BYETTA contains

250 microgram/mL of exenatide as the active ingredient. It also contains:

- acetic acid - glacial
- meta-Cresol
- mannitol
- sodium acetate
- water for injection

Supplier

Eli Lilly Australia Pty Limited.

112 Wharf Road

West Ryde, NSW 2114

Eli Lilly New Zealand Limited

Auckland, New Zealand

Australian Registration Number:

BYETTA 5 (exenatide 5 microgram/20 microlitre),

AUST R 123609

BYETTA 10 (exenatide 10 microgram/40 microlitre),

AUST R 123610

Further information

Your food and exercise plan, along with your periodic blood sugar testing and scheduled A1C (also known as HbA1C) checks, will continue to be important in managing your diabetes while you are taking BYETTA.

You can get more information about diabetes from Diabetes Australia:

- freecall helpline 1300 136 588
- www.diabetesaustralia.com.au

Diabetes New Zealand

- toll free helpline 0800 DIABETES (0800 342 238)
- www.diabetes.org.nz

This leaflet was prepared in February 2012

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