

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BYETTA?

BYETTA contains the active ingredient exenatide. BYETTA is used to improve blood sugar control in adults with type 2 diabetes mellitus. For more information, see Section [1. Why am I using BYETTA?](#) in the full CMI.

2. What should I know before I use BYETTA?

Do not use if you have ever had an allergic reaction to BYETTA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use BYETTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BYETTA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use BYETTA?

- 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.
- 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

More instructions can be found in Section [4. How do I use BYETTA?](#) in the full CMI.

5. What should I know while using BYETTA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using BYETTA• Use BYETTA as prescribed by your doctor
Things you should not do	<ul style="list-style-type: none">• Do not stop using BYETTA without checking with your doctor• If you stop taking BYETTA suddenly your condition may worsen or you may have unwanted side effects such as drowsiness, weakness, confusion, irritability, hunger, fast heartbeat, sweating (hypoglycaemia)
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol• Alcohol may mask the symptoms of hypoglycaemia or make it worse
Looking after your medicine	<ul style="list-style-type: none">• Keep your unopened BYETTA pen in the refrigerator where the temperature stays between 2-8°C. Do not freeze. Do not use BYETTA if it has been frozen.• You may keep your BYETTA pen below 25°C for up to 30 days while you are using the pen. Do not put your BYETTA pen near heat or in the sun.

For more information, see Section [5. What should I know while using BYETTA?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation. Tell your doctor if you experience any side effects and they concern you.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

BYETTA®

Active ingredient: *exenatide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BYETTA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BYETTA.**

Where to find information in this leaflet:

- [1. Why am I using BYETTA?](#)
- [2. What should I know before I use BYETTA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BYETTA?](#)
- [5. What should I know while using BYETTA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using BYETTA?

BYETTA contains the active ingredient exenatide. BYETTA belongs to a group of medicines called glucose lowering medicines.

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
- a combination of metformin and a sulfonylurea
- a combination of metformin and a long-acting insulin

Diabetes 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.

BYETTA is not recommended for patients under 18 years of age.

2. What should I know before I use BYETTA?

Warnings

Do not use BYETTA if:

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

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have allergies to any other medicines or foods
- have any other medical conditions, such as kidney problems, high blood pressure or other heart problems, high cholesterol and triglycerides (a lipid disorder involving too many fatty acids in the blood), pancreatitis, gall stones, inflammation of the gall bladder (cholecystitis), alcohol abuse

- have severe problems with your stomach or food digestion (BYETTA slows stomach emptying, so food passes more slowly through your stomach)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Use of BYETTA in pregnancy is limited. Your doctor can discuss the risk and benefits with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if this medicine passes into your breast milk. Your doctor can discuss the risk and benefits with you.

3. What if I am taking other medicines?

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

Some medicines may interfere with BYETTA and affect how it works. These include:

- medicines that need to pass through the stomach quickly for absorption (BYETTA slows stomach emptying and can affect these medicines)
- other medicines used to stimulate insulin secretion to control your blood sugar levels
- bisphosphonates - a type of medicine used to treat osteoporosis
- tetracyclines
- statins - a type of medicine used to lower cholesterol
- oral contraceptives or oral antibiotics - these should be taken at least 1 hour before taking BYETTA
- warfarin - a medicine used to prevent blood clots (taking BYETTA while you are taking warfarin may cause you to bleed more easily)

You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking other medicines.

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:

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

Using BYETTA with the following medicines may affect your kidneys:

- 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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BYETTA.

4. How do I use BYETTA?

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

Ask your doctor or healthcare professional which needle length and gauge is best for you. Needles are not included with the 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

Follow the instructions provided by your doctor or healthcare professional.

If you are also taking insulin, you must inject your insulin at a separate site from your BYETTA injection

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.
- 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.
- Use BYETTA as prescribed by your doctor

When to use BYETTA

- 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 use BYETTA after your meal

If you forget to use BYETTA

If you miss a dose of BYETTA, skip that dose and inject your next dose at the next prescribed time.

Do not inject an extra dose or increase the amount of your next dose to make up for the one you missed.

Ask your doctor or 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 use too much BYETTA

If you think that you have used too much BYETTA, you may need urgent medical attention. Symptoms of an overdose may include nausea, vomiting, dizziness, or symptoms of low blood sugar.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 76 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BYETTA?

Things you should 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 BYETTA.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using BYETTA. It may affect other medicines used during surgery.

If you become pregnant while using BYETTA, 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.

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

Some symptoms of hypoglycaemia are:

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

If you are experiencing any 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.

Call your doctor straight away if you:

- become pregnant while using BYETTA

Remind any doctor, dentist or pharmacist you visit that you are using BYETTA.

Things you should not do

- do not use the BYETTA pen if you see solid particles or if the solution is cloudy or coloured
- do not use BYETTA if the pen has been in use for 30 days, even if there is medicine left in the pen
- do not stop using BYETTA or change your dosage unless your doctor tells you to
- do not use BYETTA if you think it has been frozen or exposed to excessive heat (it will not work as it should)
- do not use BYETTA to treat any other conditions unless your doctor tells you to
- do not give BYETTA to anyone else, even if they have the same condition as you

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 using BYETTA.

You can get more information about diabetes from:

Diabetes Australia

- free call helpline 1300 136 588
- www.diabetesaustralia.com.au

Diabetes New Zealand

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BYETTA affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol. Alcohol may mask the symptoms of hypoglycaemia or make it worse.

Looking after your medicine

- Keep BYETTA where young children cannot reach it
- Keep your unopened BYETTA pen in the refrigerator where the temperature stays between 2-8°C. Do not freeze. Do not use BYETTA if it has been frozen.
- You may keep your BYETTA pen below 25°C for up to 30 days while you are using the pen. Do not put your BYETTA pen near heat or in the sun.
- Remove the needle immediately after you have given your injection.
- 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 BYETTA pen after 30 days, even if it contains some unused solution

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

When to discard your medicine

Discard BYETTA if your doctor tells you to stop taking it or the expiry date has passed. Do not use BYETTA after the expiry date, if the packaging is torn or shows signs of tampering.

Getting rid of any unwanted medicine

If you no longer need to use BYETTA or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nausea• vomiting• diarrhoea• dizziness or light headedness• headache• feeling jittery• acid stomach• abdominal pain or bloating• loss of energy and strength• redness, swelling or itching at the injection site (local allergy)• indigestion or stomach ache• excessive sweating• loss of appetite• weight loss	Speak to your doctor if you have any of these less serious side effects and they worry you.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

Tell your doctor if you experience hypoglycaemia.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• rapid weight loss (>1.5 kg per week)• passing little or no urine• taste disturbance or loss of taste• drowsiness or loss of consciousness• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (anaphylaxis)• stomach discomfort relieved by belching or passing wind• persistent constipation with cramping and abdominal pain -may also include a persistent	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<p>swollen abdomen, inability to pass gas, nausea, or vomiting (intestinal obstruction including ileus)</p> <ul style="list-style-type: none"> • hives, pinkish, itchy swellings on the skin or itchy red raised skin rash • bleeding more easily than normal if you are taking warfarin • persistent and severe abdominal pain and vomiting and/or diarrhoea and/or nausea (acute pancreatitis) • sudden and intensifying abdominal pain that may spread to your shoulders or back which may include yellowing of the skin and eyes (cholelithiasis or cholecystitis) 	

The above list includes serious side effects that require medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What BYETTA contains

Active ingredient (main ingredient)	exenatide
Other ingredients (inactive ingredients)	glacial acetic acid, metacresol, mannitol, sodium acetate, water for injection

Do not take this medicine if you are allergic to any of these ingredients.

What BYETTA looks like

BYETTA is a clear colourless liquid. It is supplied in a 5 microgram (AUST R 123609) or 10 microgram (AUST R 123610) pre-filled delivery device (pen). Each pen contains dosing for 30 treatment days.

BYETTA is available in packs of 1 pen.

Who distributes BYETTA

Supplied in Australia by

AstraZeneca Pty Ltd
ABN 54 009 682 311

66 Talavera Road
Macquarie Park NSW 2113

Telephone: 1800 805 342

Supplied in New Zealand by

AstraZeneca Limited
Auckland

Telephone: 09 306 5650

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