Bydureon®

exenatide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BYDUREON.

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BYDUREON 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 BYDUREON is used for

BYDUREON is an injectable medicine used to improve blood sugar control in adults with type 2 diabetes mellitus.

BYDUREON is used with other medicines for type 2 diabetes mellitus when they are not enough to control your blood sugar level, along with diet and exercise.

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

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

BYDUREON 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 BYDUREON

When you must not use it

Do not use BYDUREON if:

- you have type 1 diabetes or diabetic ketoacidosis (often caused by very high blood glucose levels)
- you are allergic to exenatide 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 BYDUREON 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.

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

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.
BYDUREON 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 BYDUREON or may affect how it works. You may need different amounts of your medicines or you may need to take different medicines.

These include:

- warfarin, a medicine used to prevent blood clots. Taking BYDUREON 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 BYDUREON while you are taking these medicines may affect your kidneys
- orlistat, a weight loss medicine
- opioids, a narcotic commonly used as a pain killer
- anticholinergics, a type of medicine used to relieve stomach cramps or spasms, to treat travel sickness and to treat Parkinson's disease
- when using BYDUREON in combination with sulfonylureas, you may need to adjust the dose of the sulfonylurea to avoid hypoglycaemia
- use of BYDUREON with insulins or other GLP-1 receptor agonists (e.g. BYETTA) is not recommended

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

How to use BYDUREON

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.

How to use it

BYDUREON is supplied in three presentations:

- BYDUREON kit - containing a vial and syringe
- BYDUREON pre-filled pen
- BYDUREON BCise autoinjector

Your healthcare professional should teach you how to use the BYDUREON kit, pen or autoinjector.

Remove the BYDUREON kit, pen or autoinjector from the refrigerator and rest it flat for at least 15 minutes prior to use.

BYDUREON kit and pen is provided as a powder that must be mixed with a diluent (solvent) before use. Only mix BYDUREON with the diluent if the diluent is clear and free of particles.
Once you have mixed BYDUREON with the diluent, the mixture should be white to off - white, have no clumps and be uniformly cloudy.

BYDUREON kit or pen must be injected immediately after mixing with the diluent.

BYDUREON BCise autoinjector is provided as a suspension that should be white to off-white and cloudy.
Mix the suspension by shaking hard for at least 15 seconds. Use the suspension only if it is evenly mixed.

If you see white medicine on the sides, bottom or top of the autoinjector window, the medicine is NOT mixed well.
Shake hard again until mixed well.

BYDUREON BCise autoinjector must be injected immediately after mixing the suspension.

Read the User Manual for information on how to use the BYDUREON kit, pen or autoinjector before use.

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

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

Use a new BYDUREON kit, pen or autoinjector for each injection and dispose of it after use.

This medicine is for you only. Never share BYDUREON with others.

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

How much to use

Each BYDUREON kit, pen or autoinjector contains one dose, you should use the full dose each time you inject.

BYDUREON needs to be injected only once per week.

Use BYDUREON exactly as prescribed by your doctor.

When to use it

Inject BYDUREON once a week, at any time of the day, with or without meals.

You may wish to choose a specific day of the week that will be your BYDUREON injection day.

How long to use it

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

If you forget to use it

If you miss a dose of BYDUREON and there is at least 3 days until your next dose, you should take it as soon as you remember.

If you miss a dose of BYDUREON and there is 1 or 2 days until your next dose, you should wait until your next regularly scheduled dose to take it.

The next weekly dose can be taken on the preferred day of the week as long as it is at least 3 days after the last dose was taken.

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

If you are not sure if you have taken your entire dose, do not inject another dose of BYDUREON. Wait until your next weekly dose is due.

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 BYDUREON, immediately call your doctor or the Poisons Information Centre (telephone AU: 13 11 26, 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 BYDUREON

Things you must do

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

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

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 BYDUREON 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.

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 BYDUREON in combination with sulfonylureas, 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 BYDUREON.

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

Tell your doctor if you experience hypoglycaemia.

Tell your doctor if you experience worsening blood sugar control.

Tell your doctor if you notice any of the following:

- nausea
- vomiting
- diarrhoea
- constipation
- 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)
- a lump or hardening under the skin at the injection site
- indigestion (dyspepsia)
- excessive sweating (hyperhidrosis)
- mood changes
- flu-like symptoms
- bone or muscle pain

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

BYDUREON may reduce your appetite. Nausea and vomiting were very commonly reported in patients using BYDUREON. 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
- serious skin reactions at the injection site, including ulcer, swollen cavity containing pus (abscess) or red area of skin that feels hot and tender (cellulitis)
- bleeding more easily than normal, if you are taking warfarin

These are rare or very rare side effects of BYDUREON. 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 BYDUREON.

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 BYDUREON

Storage

Keep BYDUREON in the refrigerator where the temperature stays between 2-8°C. Do not freeze. Do not use BYDUREON if it has been frozen.

BYDUREON must be stored flat.

Keep this medicine where children cannot reach it.

Each BYDUREON kit, pen or autoinjector contains one dose, you should use the full dose each time you inject.

Use a new BYDUREON kit, pen or autoinjector for each injection and dispose of it after use.

BYDUREON can be kept out of the refrigerator (below 30°C) for a total of 4 weeks.

Discard the used BYDUREON components, including the needle, immediately after use.

Ask your pharmacist how to discard BYDUREON.

BYDUREON is for use in a single patient only.

Disposal

Dispose of your BYDUREON kit, pen or autoinjector with the needle still attached into a yellow plastic sharps container or similar puncture proof container composed of hard plastic or glass (the needle is hidden in the autoinjector).

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

BYDUREON kit
BYDUREON powder is white to off-white. The diluent is a clear colourless to pale yellow to pale brown liquid. When mixed together, the solution is white to off-white and cloudy.

BYDUREON is supplied in a kit containing a vial of exenatide powder, a syringe of diluent (solvent), an adapter and 2 needles (1 spare). Each kit contains dosing for 1 week of treatment as a single dose.

BYDUREON kit is supplied in a pack of 4 single dose kits.

BYDUREON pen
BYDUREON powder is white to off-white. The diluent is a clear colourless to pale yellow to pale brown liquid. When mixed together, the solution is white to off-white and cloudy.

BYDUREON is supplied in a dual-chambered pen containing exenatide powder in one chamber and diluent (solvent) in the other chamber for suspension.

Each pre-filled pen is provided with one custom needle. Each pack also contains one spare needle.

Each pen contains dosing for 1 week of treatment as a single dose.

BYDUREON pen is supplied in a pack of either 4 single dose pens or 1 single dose pen.

BYDUREON BCise autoinjector
BYDUREON suspension is white to off-white and cloudy

BYDUREON is supplied in an autoinjector containing a suspension of exenatide.

Each autoinjector contains dosing for 1 week of treatment as a single dose.

BYDUREON BCise autoinjector is supplied in a pack of either 4 single dose autoinjectors or 1 single dose autoinjector.

Ingredients

BYDUREON powder contains 2 mg of exenatide as the active ingredient. It also contains polyglactin and sucrose.

The diluent contains:

- carmellose sodium
- sodium chloride
- polysorbate 20
- monobasic sodium phosphate monohydrate
- dibasic sodium phosphate (as heptahydrate)
- sodium hydroxide (pen only)
- water for injection

BYDUREON BCise autoinjector - the suspension contains 2 mg of exenatide as the active ingredient. It also contains polyglactin, sucrose and medium chain triglycerides.

Suppliers

Supplied in Australia by

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
Macquarie Park NSW 2113

Supplied in New Zealand by

AstraZeneca Limited
Auckland

For all enquiries contact AstraZeneca by calling 1800 805 342 (Australia) or 09 306 5650 (New Zealand)

Australian Registration Numbers

The Australian Registration Numbers for BYDUREON are:

BYDUREON Kit - AUST R 175504

BYDUREON Pen - AUST R 235962

BYDUREON BCise autoinjector - AUST R 298869

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 BYDUREON.

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

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