

Bydureon[®]

Exenatide 2 mg powder and solvent for prolonged-release suspension for injection

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Bydureon**. It does not contain all the information that is known about **Bydureon**.

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 will have 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, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is Bydureon is used for

Bydureon contains the active ingredient exenatide. It is an injectable medicine used to improve blood sugar control in adults with type 2 diabetes mellitus. It 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.

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 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 **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.

Using this medicine in combination with a sulphonylurea can cause low blood sugar (hypoglycaemia). Ask your doctor, pharmacist, or diabetes nurse if you are not sure if any of your other medicines contain a sulphonylurea.

Tell your doctor if you are pregnant or plan to become pregnant. Information on 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 sulphonylureas, you may need to adjust the dose of the sulphonylurea to avoid hypoglycaemia
- use of **Bydureon** with insulins or other GLP-1 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 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 and cloudy. **Bydureon must be injected immediately after mixing with the diluent.**

Bydureon comes as either a kit containing a vial and syringe or a dual chamber pen. Your health care professional should teach you how to use the **Bydureon** kit or pen.

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

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 injection needle for each injection and dispose of it after each use.

This medicine is for you; never share **Bydureon** with others.

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

Never mix insulin and **Bydureon** together in the same injection. If you need to give yourself both at the same time, use two separate injections. You may give both injections in the same body area (for example, your stomach area), but you should not give the injections next to each other.

How much to use

Each Bydureon kit or pen contains a single 2mg dose. The whole dose should be mixed with the diluent for each injection. **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 day, with or without meals. You might like to choose a day that you always plan to take your **Bydureon** injection.

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, take your injection as soon as possible after you notice provided your scheduled next dose is at least 3 days away. 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 National Poisons Centre (telephone 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 a sulphonylurea, hypoglycaemia can occur. The dose of your sulphonylurea 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 a sulphonylurea, 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 a sulphonylurea, hypoglycaemia can occur. Tell your doctor if you experience hypoglycaemia.

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 your **Bydureon** kit or pen in the refrigerator where the temperature stays between 2 - 8 °C. Do not freeze. Do not use **Bydureon** if it has been frozen. You may keep your **Bydureon** kit or pen out of the refrigerator (below 30 °C) for up to 30 days prior to use. Do not put your **Bydureon** kit or pen near heat or in the sun.

After reconstitution the suspension must be injected immediately.

Keep this medicine where children cannot reach it.

Disposal

Dispose of your syringe or pen with the needle still attached safely into a yellow plastic sharps container or similar puncture proof container composed of hard plastic or glass.

You do not need to keep any part of the **Bydureon** kit or pen.

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

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

Bydureon Kit: Each single-dose kit consists of one vial containing 2 mg exenatide powder, one pre-filled syringe containing 0.65 mL solvent, one vial connector, and two injection needles. One needle is a spare.

Bydureon Pen: Each single dose pen 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 is available in packs of 4 single dose kits or 4 single dose pens.

Ingredients

Powder

- Exenatide 2 mg as the active ingredient
- Poly (D,L-lactide-co-glycolide)
- Sucrose

Solvent

- Carmellose sodium
- Sodium chloride
- Polysorbate 20
- Monobasic sodium phosphate, monohydrate
- Dibasic sodium phosphate, heptahydrate
- Sodium hydroxide (pen only)
- Water for injections

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 New Zealand on toll free helpline 0800 DIABETES (0800 342 238) or from www.diabetes.org.nz

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