Package Leaflet: Information for the user

Bydureon 2 mg powder and solvent for prolonged-release suspension 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.

What is in this leaflet

1. What Bydureon is and what it is used for

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

This medicine is used in combination with the following diabetes medicines: metformin, sulphonylureas, thiazolidinediones, SGLT2 inhibitors and/or a long-acting insulin. Your doctor is now prescribing this medicine 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 your body is not able to use the insulin properly. This medicine helps your body to increase the production of insulin when your blood sugar is high.

2. What you need to know before you use Bydureon

Do not use Bydureon
- 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 Bydureon about the following:

- If you use this medicine in combination with a sulphonylurea, as low blood sugar (hypoglycaemia) can occur. Test your blood glucose levels regularly. 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, as this medicine should not be used.

- How to inject this medicine. It should be injected into the skin and not into a vein or into the muscle.
- If you have severe problems with your stomach emptying (including gastroparesis) 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 1.5 kg 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.

Bydureon 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 Bydureon
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, particularly:
- other medicines that are used to treat type 2 diabetes such as medicines that work like Bydureon (for example: liraglutide or other exenatide containing products), as taking these medicines with Bydureon 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.
- a medicine that contains a sulphonylurea, as low blood sugar (hypoglycaemia) can occur when combined with Bydureon.
- 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).

Pregnancy and breast-feeding
It is not known if this medicine may harm your unborn child, therefore you should not use it during pregnancy and for at least 3 months before a planned pregnancy.

It is not known if exenatide passes into your milk. You should not use this medicine while breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should use contraception if you could potentially become pregnant during treatment with this medicine.

Driving and using machines
If you use this medicine in combination with a sulphonylurea, 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).

Important information about some of the ingredients of Bydureon
This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium-free”.

3. How to use Bydureon

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.

You should inject this medicine once a week, at any time of day, with or without meals.

You should inject this medicine into the skin (subcutaneous injection) of your stomach area (abdomen), upper leg (thigh), or the back of your upper arm. Do not inject into a vein or muscle.

Each week you can use the same area of your body. Be sure to choose a different injection site in that area.

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.

Test your blood glucose levels regularly, it is particularly important to do this if you are also using a sulphonylurea.

Follow the "Instructions for the User" provided in the carton to inject Bydureon

Your doctor or diabetes nurse should teach you how to inject this medicine before you use it for the first time.

Remove one pen from the refrigerator and let it stand at room temperature for at least 15 minutes. Check that the liquid in the pen is clear and free of particles before you begin. After mixing the liquid with the powder, use the suspension only if the mixture is white to off white and cloudy. If you see clumps of dry powder on the sides of the pen, the medicine is NOT mixed well. Tap vigorously again until well mixed.

You should inject this medicine immediately after mixing the powder and the solvent.

Use a new pen for each injection. You should dispose of the pen safely, with the needle still attached, after use, as instructed by your doctor or diabetes nurse.

If you use more Bydureon than you should
If you use more of this medicine than you should, please consult with your doctor first as you may need medical treatment. 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 Bydureon
You might like to choose a day that you always plan to make your Bydureon injection.

If you miss a dose and there are 3 days or more until your next dose is due, then take the missed dose as soon as it is possible to do so. For your next injection you can return to your chosen injection day. If you miss a dose and there are only 1 or 2 days until your next dose is due, skip the missed dose and take the next one as usual, on the day it is due. You can also change your chosen injection day, as long as your last dose was given 3 or more days before.

Do not take two doses of Bydureon within 3 days of each other.

If you are not sure you have taken the full dose of Bydureon
If you are not sure if you have taken all of your dose, do not inject another dose of this medicine, just take it next week as planned.

If you stop using Bydureon

If you feel you should stop using this medicine, please 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)
- Hypersensitivity (rashes, itching and rapid swelling of the tissues of the neck, face, mouth or throat)
- Difficulty with swallowing
- Hives and difficulty with breathing

Cases of inflammation of the pancreas (pancreatitis) have been reported uncommonly (may affect up to 1 in 100 people) 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 the risk 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)
- diarrhoea
- hypoglycaemia (low blood sugar) when taken with a medicine that contains a **sulphonylurea.**

When this medicine is used with a medicine that contains a **sulphonylurea**, episodes of low blood sugar (hypoglycaemia, generally mild to moderate) can occur. The dose of your sulphonylurea 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)
- hypoglycaemia (low blood sugar) when taken with an insulin
- dizziness

- headache
- vomiting
- loss of energy and strength
- tiredness (fatigue)
- constipation
- pain in the stomach area
- bloating
- indigestion
- flatulence (passing gas)
- 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 1.5 kg per week) talk to your doctor about it since this may cause problems such as gallstones.

- injection site reactions

If you have an injection site reaction (redness, rash, or itching) you may like to ask your doctor for something to help relieve any signs or symptoms. You may see or feel a small bump under the skin after your injection; it should go away after 4 to 8 weeks. You should not need to stop your treatment.

Uncommon side effects

- decrease in kidney function
- dehydration, sometimes with a decrease in kidney function
- intestinal obstruction (blockage in intestine)
- burping
- unusual taste in the mouth
- increased sweating
- hair loss
- sleepiness

Rare side effects

- feeling jittery

Not known (frequency cannot be estimated from the available data)
In addition some **other side effects** have been reported.

- changes in INR (measurement of blood thinning) have been reported when used together with warfarin.
- skin reactions at the injection site following injection of exenatide. These include: cavity containing pus (abscess) and swollen, or red area of skin that feels hot and tender (cellulitis).

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace

IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Bydureon

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2°C to 8°C). Do not freeze.
The pen may be kept for up to 4 weeks below 30ºC prior to use.
Store in the original package in order to protect from light.
Throw away any Bydureon pen that has been frozen.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bydureon contains
- The active substance is exenatide. Each pre-filled pen contains 2 mg of exenatide. After suspension, the delivered dose is 2 mg/0.65 ml.
- The other ingredients are:
- In the powder: poly (D,L-lactide-co-glycolide) and sucrose.
- In the solvent: carmellose sodium, sodium chloride, polysorbate 20, sodium dihydrogen phosphate monohydrate, disodium phosphate heptahydrate, water for injection and sodium hydroxide (for pH adjustment).

What Bydureon looks like and contents of the pack

This medicine is provided as a powder and solvent (liquid) for suspension for injection in a pre-filled pen. The powder (2 mg) in one chamber, is white to off-white and the solvent (0.65 ml) in the other chamber, is a clear, colourless to pale yellow to pale brown solution. Each single-dose pre-filled pen is provided with one custom needle. Each carton also contains one spare needle.

This medicine is available in a pack of 4 single-dose pre-filled pens, and a multipack containing 12 (3 packs of 4) single-dose pre-filled pens. Not all pack sizes may be marketed.

Marketing Authorisation Holder
AstraZeneca AB
SE-151 85 Södertälje
Sweden

Manufacturer

AstraZeneca AB
Gärtunavägen
SE-151 85 Södertälje
Sweden

AstraZeneca UK Limited
Silk Road Business Park,
Macclesfield, Cheshire, SK10 2NA
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
AstraZeneca UK Ltd
Tel: +44 1582 836 836

Ireland
AstraZeneca Pharmaceuticals (Ireland) DAC
Tel: +353 1609 7100

Malta
Associated Drug Co. Ltd
Tel: +356 2277 8000

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Other sources of information

Detailed information on this medicine is available on the website of the European Medicines Agency http://www.ema.europa.eu/

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