Ozempic®

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Ozempic®?

Ozempic® contains the active ingredient semaglutide. Ozempic® is used in adults with type 2 diabetes mellitus to lower blood sugar (glucose), and if you also have chronic kidney disease, it reduces the risk of your kidney disease worsening.
For more information, see Section 1. Why am I using Ozempic®? in the full CMI.

2. What should I know before I use Ozempic®?

Do not use if you have ever had an allergic reaction to semaglutide 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 Ozempic®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ozempic® 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 Ozempic®?

- Ozempic® is an injection that is used once a week.
- When you first start using Ozempic®, the starting dose is 0.25 mg once a week for four weeks, after four weeks you should increase your dose to 0.5 mg once a week. If your blood sugar is not controlled well enough, your doctor may further increase your dose to 1 mg and then to 2 mg once a week, if needed.
- Inject Ozempic® under the skin as shown to you by your doctor or diabetes education nurse.

More instructions can be found in Section 4. How do I use Ozempic®? in the full CMI.

5. What should I know while using Ozempic®?

Things you should do	• Remind any doctor, dentist, pharmacist or diabetes education nurse you visit that you are using Ozempic®. • If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice.
Things you should not do	• Do not stop using this medicine suddenly. If you stop using it, your blood sugar levels may increase. • Do not use this medicine if you think it has been frozen or exposed to excessive heat.
Driving or using machines	• Low blood sugar (hypoglycaemia) may affect your ability to concentrate. Avoid driving or using machines if you get any

	signs of low blood sugar, including dizziness.
Drinking alcohol	• Alcohol may mask the symptoms of hypoglycaemia or make it worse.
Looking after your medicine	• Before opening: store in a refrigerator (2°C to 8°C). Keep away from the cooling element. Do not freeze. • During use: you can keep it for 6 weeks *either* at room temperature (not above 30°C), *or* in a refrigerator (2°C to 8°C), away from the cooling element. Do not freeze.

For more information, see Section 5. What should I know while using Ozempic®? in the full CMI.

6. Are there any side effects?

The most common side effects when using Ozempic® are diarrhoea and nausea. Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away, allergic reaction (skin rashes over a large part of the body, shortness of breath, wheezing, swelling of the face, lips

or tongue, fast pulse, sweating), loss of vision and bowel obstruction are very serious side effects for which you may need urgent medical attention.
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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.
You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Ozempic®

Active ingredient(s): *semaglutide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ozempic®. **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 Ozempic®.**

Where to find information in this leaflet:

1. Why am I using Ozempic®?
2. What should I know before I use Ozempic®?
3. What if I am taking other medicines?
4. How do I use Ozempic®?
5. What should I know while using Ozempic®?
6. Are there any side effects?
7. Product details

1. Why am I using Ozempic®?

Ozempic® contains the active ingredient semaglutide. Ozempic® belongs to a group of medicines called 'GLP-1 receptor agonists' which help control how the pancreas works.

Ozempic® is an injection that is used once a week.

Ozempic® is used to lower blood sugar (glucose) in adults with type 2 diabetes mellitus.

Ozempic® is also used to reduce the risk that your kidney disease worsens if you have type#2#diabetes and chronic kidney disease.

Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control the level of sugar in your blood or, your body is not able to use the insulin it makes properly.

Ozempic® helps your body to produce more insulin when your blood sugar level is high.

Ozempic® is used on its own if your blood sugar is not properly controlled by diet and exercise alone. Ozempic® is also able to be used with other medicines for diabetes when they are not enough to control your blood sugar levels. These medicines may include oral antidiabetics (such as metformin, thiazolidinedione medicines (TZD's), sulfonylurea medicines, SGLT2 inhibitor medicines such as Jardiance®) or insulin.

It is important that you keep following any diet and lifestyle advice from your doctor, diabetes education nurse or pharmacist while using Ozempic®.

Ozempic® has not been studied in children and should not be used in children or adolescents under 18 years.

Ozempic® is not addictive.

2. What should I know before I use Ozempic®?

Warnings

Do not use Ozempic® if:

- you are allergic to semaglutide, or any of the ingredients listed at the end of this leaflet
  Some of the symptoms of an allergic reaction may include:
  - redness, swelling, rash and itching at the injection site
  - rash, itching or hives on the skin
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body.
- it is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering
- it has expired or is damaged, return it to your pharmacist for disposal. The expiry date refers to the last day of that month.

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

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

Check with your doctor if you:

- have any other medical conditions including a history of diabetic retinopathy or pancreatitis.
- are also taking a sulfonylurea (such as glimepiride or glibenclamide) or insulin. Your doctor may tell you to test your blood sugar levels. This will help your doctor to decide if the dose of the sulfonylurea or insulin needs to be changed to avoid you getting hypoglycaemia (low blood sugar).
- have or have had depression, suicidal thoughts or any other major mental illness.
- 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, think you are pregnant, or intend to become pregnant.

Ozempic® should not be used during pregnancy and for at least two months before a planned pregnancy because Ozempic® may harm your unborn child. If you could become pregnant while using Ozempic®, it is recommended to use contraception.

Do not use Ozempic® if you are breast-feeding. It is not known if Ozempic® passes into breast milk.

Type 1 diabetes/ketoacidosis

- Ozempic® should not be used if you have type 1 diabetes or diabetic ketoacidosis (a complication of diabetes that happens when the body is not able to break down glucose because there is not enough insulin). Ozempic® is not an insulin.

Please consult your doctor if the above applies to you.

Food or liquid getting into lungs during anaesthesia

- Some patients taking medicines like Ozempic® have had problems with food or liquid from their stomach getting into their lungs while under general anaesthesia or deep sedation.
- Tell your healthcare professional that you are taking Ozempic® before you have a procedure that requires general anaesthesia or deep sedation.

Acute pancreatitis

- If you experience symptoms of acute pancreatitis, like persistent, severe abdominal pain, you should consult your doctor.

Stomach and gut problems and dehydration

- Drink plenty of fluids to avoid dehydration if you experience vomiting or diarrhoea when beginning treatment with Ozempic®
- Dehydration can lead to kidney problems, particularly in patients who have pre-existing kidney disease
- If you notice your urine changes appearance or you produce urine less frequently, see your doctor.

Patients with delayed stomach emptying (gastroparesis)

- If you have slow (delayed) stomach emptying (called gastroparesis), use of Ozempic® may lead to serious or severe gastrointestinal adverse events. Talk to your doctor before using Ozempic®.

Sudden changes to your eyesight

- If you notice a sudden loss of vision or rapidly worsening eyesight during treatment with this medicine, immediately contact your doctor for advice. This may be caused by a very rare side effect called non-arteritic anterior ischaemic optic neuropathy (NAION). Your doctor may refer you for an eye examination and you may have to stop treatment with this medicine. See additional information under Section 6. Are there any side effects?

3. What if I am taking other medicines?

Tell your doctor, pharmacist or diabetes education nurse if you are taking, have recently taken, or might take, any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

In particular, tell your doctor, pharmacist or nurse if you are using medicines containing any of the following:

- a sulfonylurea (such as glimepiride or glibenclamide)
- insulin.

Combining these medicines with Ozempic®
might increase the risk of getting low blood sugar (hypoglycaemia or a “hypo”). Please see section 6 for the warning signs of low blood sugar. Your doctor may tell you to test your blood sugar levels. This will help your doctor decide if the dose of the sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Check with your doctor, pharmacist, or diabetes education nurse if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ozempic®.

4. How do I use Ozempic®?

How much to use

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine.

Carefully follow all the directions.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

Your doctor or diabetes education nurse will tell you how much of this medicine you need to use.

- When you first start using Ozempic®, the starting dose is 0.25 mg once a week for four weeks.
- After four weeks you should increase your dose to 0.5 mg once a week. **Talk to your doctor before increasing your dose.**
- Your doctor may increase your dose to 1 mg if your blood sugar is not controlled well enough with a dose of 0.5 mg once a week.
- Your doctor may increase your dose to 2 mg once a week if your blood sugar is not controlled well enough with a dose of 1 mg once a week.
- Follow the instructions provided and use Ozempic® until your doctor tells you to stop. **Do not change your dose unless your doctor has told you to.** Any

change in dose should be made cautiously and only under medical supervision.

- Do not stop using Ozempic® unless your doctor tells you to. If you stop using it, your blood sugar levels may increase.

When to use Ozempic®

- You should use Ozempic® once a week on the same day each week if possible.
- You can give yourself the injection at any time of the day - regardless of meals.
- To help you remember to inject Ozempic® once a week only, it is recommended to note the chosen weekday (e.g. Wednesday) on the carton. You can also write the date on the carton every time you have injected Ozempic®.
- If necessary, you can change the day of your weekly injection of Ozempic® as long as it has been at least 3 days since your last injection of Ozempic®.

How to use Ozempic®

- Inject Ozempic® under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse. Never inject Ozempic® into a vein or muscle.
- Ozempic® may be injected into the front of your waist (abdomen), the front of your thigh, or your upper arm.
- Before you use the pen for the first time, your doctor or diabetes education nurse will show you how to use it.

Follow the detailed instructions on how to inject Ozempic® in the instructions for use supplied with the product. These instructions are also available for the marketed presentations via the following hyperlinks:
If you use Ozempic 0.25, 0.5 mg in 1.5 mL pen (AUST R 308324): https://medsinfo.com.au/media/noiozemp
If you use Ozempic 0.25, 0.5 mg in 3 mL pen (AUST R 446290): https://medsinfo.com.au/media/noiozem3
If you use Ozempic 1 mg (AUST R 315107): https://medsinfo.com.au/media/noiozem1

Checking your Ozempic® pen:

Ozempic® should be clear and colourless, or almost colourless.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Ozempic® should not be used if it has been frozen.

Read the instructions printed with this leaflet carefully in order to prepare and handle your Ozempic® pen correctly.

If you forget to use Ozempic®

You should use Ozempic® once a week on the same day each week if possible.

If you forget a dose and:

- it is 5 days or less since you should have used Ozempic®, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.

- it is more than 5 days since you should have used Ozempic®, skip the missed dose. Then inject your next dose as usual on your scheduled day.

Do not take an extra dose or increase the dose to make up for a missed dose.

If you use too much Ozempic®

If you use more Ozempic® than you should, you may get side effects such as feeling sick (nausea) or being sick (vomiting), or diarrhoea.

If you think that you have used too much Ozempic®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), contact your doctor, or
- go to the Accident and 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 Ozempic®?

Things you should do

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

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

Ask them 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 not be able to get Ozempic® in the country you are visiting.

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

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

Things you should not do

- Do not stop using your medicine unless your doctor tells you to. If you stop using it, your blood sugar levels may increase.
- Do not use this medicine if you think it has been frozen or exposed to excessive heat. It will not work as well.
- 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.
- Do not share your pen or needles with anyone else.

Hypoglycaemia

Tell your doctor if you often have hypos (low blood sugar levels). When Ozempic® is used with a sulfonylurea (such as glimepiride or glibenclamide) or with insulin, hypos can occur. The dose of your sulfonylurea or insulin may need to be reduced while you take Ozempic®.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice.

Driving or using machines

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

Low blood sugar (hypoglycaemia) may affect your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar, including dizziness. See section 6 for the warning signs of low blood sugar. Talk to your doctor for further information.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Storage

Before opening:

Keep your unopened Ozempic® pens in a refrigerator (2°C to 8°C). Keep away from the cooling element. Do not freeze.

During use:

While you are using your Ozempic® pen you can keep it for 6 weeks **either** at room temperature (not above 30°C), **or** in a refrigerator (2°C to 8°C), away from the cooling element. Do not freeze.

The medicine in Ozempic® must not be frozen or exposed to heat or direct sunlight.

When you are not using the pen, keep the pen cap on in order to protect from light.

Never use Ozempic® if the solution is not clear and colourless, or almost colourless.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the Ozempic® pen you are using after 6 weeks even if there is still some medicine left in it.

Dispose of used needles safely into a yellow plastic sharps container.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

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.

The most common side effects when using Ozempic® are diarrhoea and nausea. These side effects are usually mild and normally decrease with continued use.

Less serious side effects

Less serious side effects	What to do
General effects • decreased appetite • headache • vomiting (being sick)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• indigestion (dyspepsia) • burping, wind (flatulence) or constipation • heartburn • painful or swollen stomach (abdomen) • weight loss • injection site reactions (such as bruising, pain, irritation, itching and rash) • a delay in the emptying of the stomach • fast heart beat • feeling tired • feeling dizzy • changes to your vision or eyesight • unpleasant, abnormal or altered taste sensation • hiccups • increase in pancreas blood test results • change in skin sensation • hair loss **Other effects**	

Less serious side effects	What to do
• Tell your doctor if you experience: o gallstones o inflamed gall bladder o kidney stones o dehydration. When initiating treatment with Ozempic®, you may in some cases experience dehydration as a result of vomiting, nausea or diarrhoea. It is important to avoid dehydration by drinking plenty of fluids.	
Hypoglycaemia • low blood sugar (a hypo). Hypos are more likely to occur if you are also taking a sulfonylurea (such as glimepiride or glibenclamide) or insulin. A hypo may come on suddenly. The warning signs of a hypo can include:	**If you are already taking a sulfonylurea or insulin, your doctor may reduce the dose of these medicines before you start using Ozempic®.**

Less serious side effects	What to do
• cold sweat, cool pale skin • headache • feeling sick • feeling very hungry • changes in vision • feeling sleepy, feeling weak • feeling nervous or anxious, shaking (tremor), fast heart beat • feeling confused, difficulty concentrating.	

Serious side effects

Serious side effects	What to do
Acute pancreatitis: • Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away.	**Call your doctor straight away, or go straight to the Accident and Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
Allergic reactions (anaphylactic reactions, angioedema): • skin rashes over a large part of the body • shortness of breath, wheezing • swelling of the face, lips, tongue and/or throat with difficulty swallowing • fast pulse • sweating. **Acute kidney injury:** • passing water less often • swelling in legs, ankles, or feet • feeling sleepy • feeling short of breath • feeling very tired • feeling confused • feeling sick (nausea). **If you have any signs of sudden kidney failure, talk to a doctor straight away.** **Bowel obstruction**	

Serious side effects	What to do
• A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc. **Sudden changes to your eyesight** • A medical condition of the eye called non-arteritic anterior ischaemic optic neuropathy (NAION), which may cause loss of vision to one of your eyes without any pain. **If you notice sudden or gradually worsening eyesight, you should immediately contact your doctor.**	

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 in Australia

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 Ozempic® contains

Active ingredient **(main ingredient)**	semaglutide
Other ingredients **(inactive ingredients)**	• dibasic sodium phosphate dihydrate • propylene glycol • phenol • hydrochloric acid • sodium hydroxide • water for injections.

Potential allergens	phenol

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

What Ozempic® looks like

Ozempic® is supplied as a clear, colourless, or almost colourless solution for injection in a pre-filled pen.

Ozempic 0.25 mg, 0.5 mg solution for injection (AUST R 308324 or AUST R 446290)

One mL solution for injection contains either 1.34 mg or 0.68 mg semaglutide.

Each pen contains 1.5 mL or 3 mL of solution, delivering doses of 0.25 mg or 0.5 mg.

One pre-filled pen contains 2 mg semaglutide.

Ozempic® 0.25 mg, 0.5 mg/dose is available in a pack containing either 1 pen and 6 disposable NovoFine® Plus needles or 1 pen without disposable needles.

Ozempic 1 mg solution for injection (AUST R 315107)

One mL solution for injection contains 1.34 mg semaglutide.

Each pen contains 3 mL of solution delivering only doses of 1 mg.

One pre-filled pen contains 4 mg semaglutide.

Ozempic® 1 mg/dose is available in a pack containing either 1 pen and 4 disposable NovoFine® Plus needles or 1 pen without disposable needles.

Ozempic 2 mg solution for injection (AUST R 388180)

One mL solution for injection contains 2.68 mg semaglutide.

Each pen contains 3 mL of solution delivering only doses of 2 mg.

One pre-filled pen contains 8 mg semaglutide.

Ozempic® 2 mg/dose is available in a pack containing 1 pen and 4 disposable NovoFine® Plus needles.

*All pack sizes may not be available.

Who distributes Ozempic®

Ozempic® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10

118 Mount Street

North Sydney NSW 2060

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Further information

For further information call Novo Nordisk Customer Care on 1800 668 626 (Australia) www.novonordisk.com.au

You can also get more information about diabetes from Diabetes Australia:

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

Always check the following websites to ensure you are reading the most recent version of the Ozempic® Consumer Medicine Information:

www.novonordisk.com.au (AU)

https://www.ebs.tga.gov.au/ (AU)

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