FOUNDAYO® Tablets

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 FOUNDAYO?

FOUNDAYO contains the active ingredient orforglipron. In adults who are living with obesity or overweight, with a weight-related condition, FOUNDAYO is used together with a healthy diet and exercise for weight loss and weight maintenance. In adults with type 2 diabetes, FOUNDAYO is used to improve blood sugar control. For more information, see Section 1. Why am I using FOUNDAYO? in the full CMI.

2. What should I know before I use FOUNDAYO?

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

3. What if I am taking other medicines?

Some medicines may interfere with FOUNDAYO 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 FOUNDAYO?

- The starting dose is 0.8 mg once daily for 30 days. After 30 days, your doctor may increase your dose to the next dose. In each case your doctor will tell you to stay on a particular dose for at least 30 days before going to a higher dose.
- Swallow the tablet whole with a glass of water, do not crush, chew or split the tablet.

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

5. What should I know while using FOUNDAYO?

Things you should do	• Remind any doctor, surgeon, anaesthetist, dentist, pharmacist or nurse you visit that you are using FOUNDAYO.
Things you should not do	• Do not take more than one tablet per day. • Do not stop taking this medicine suddenly. • Do not use this medicine if the packaging is torn or shows signs of tampering. • Do not give FOUNDAYO to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how FOUNDAYO affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol. Alcohol may mask

	the symptoms of certain side effects like low blood sugar (hypoglycaemia).
Looking after your medicine	• Store below 30°C.

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

6. Are there any side effects?

The most common side effects are nausea, constipation, diarrhoea, vomiting, indigestion (dyspepsia) and abdominal pain. These side effects are usually not severe. Serious side effects which may require urgent medical attention may include inflamed pancreas (acute pancreatitis - sudden severe pain in the stomach and back), heart beating too fast (tachycardia), loss of vision and severe low blood sugar levels (severe hypoglycaemia).
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.

FOUNDAYO® Tablets

Active ingredient(s): *orforglipron (as calcium)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FOUNDAYO. **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 FOUNDAYO.**

Where to find information in this leaflet:

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

1. Why am I using FOUNDAYO?

FOUNDAYO contains the active ingredient orforglipron. Orforglipron is similar to a natural hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestine after a meal. GLP-1 works on controlling appetite and managing blood sugar levels.

Weight Management

In adults who are living with obesity or overweight, with a weight-related condition, FOUNDAYO is used together with a healthy diet and exercise for weight loss and weight maintenance.

Type 2 Diabetes

Type 2 diabetes is a condition in which your pancreas does not produce enough insulin to control your blood sugar (glucose) level.

In adults with type 2 diabetes, FOUNDAYO is used to improve blood sugar control.

You should keep following any diet and lifestyle advice from your doctor while using FOUNDAYO.

2. What should I know before I use FOUNDAYO?

Warnings

Do not use FOUNDAYO if:

- you are allergic to orforglipron, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age because it has not been studied in this age group.

Check with your doctor if you:

- have any other medical conditions such as:
  - a history of or current inflammation of the pancreas (pancreatitis) - an inflamed pancreas causing severe stomach and back pain which does not go away. FOUNDAYO may cause inflammation of the pancreas.
  - gastrointestinal disease, including severe gastroparesis (also called delayed gastric emptying), a condition affecting your digestive system. Your doctor may need to monitor your condition more closely and in some cases your doctor may need

to change or stop your dose of FOUNDAYO if symptoms are severe.

- diabetes and are using other medicines to treat your diabetes such as insulin or a sulfonylurea (another diabetes medicine). Using these medicines together with FOUNDAYO may cause low blood sugar (hypoglycaemia). Your doctor may need to change your dose of these other medicines to reduce this risk. (Refer to Section 3. What if I am taking other medicines?).
- have a problem with your eyes (diabetic retinopathy or macular oedema).
- have low blood pressure. FOUNDAYO may lead to lower blood pressure.
- have or have had depression, suicidal thoughts or any other major mental illness.
- have or have had issues with your liver, including severe liver impairment.

- take any medicines for any other condition
- know that you are due to have surgery where you will be under anaesthesia (sleeping), tell your doctor that you are taking FOUNDAYO.

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.

Do not use FOUNDAYO if you are pregnant as the effects of this medicine during pregnancy have not been studied.

If there is a chance you could become pregnant while using FOUNDAYO, it is recommended to use contraception (birth control).

It is unknown if the active ingredient, orforglipron, passes into breast milk. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Dehydration

- When starting treatment with FOUNDAYO, in some cases you may experience dehydration caused by loss of fluids due to vomiting or diarrhoea.
- Dehydration can lead to kidney problems like a decrease in kidney function. **It is important to avoid dehydration by drinking plenty of fluids**.
- Symptoms of dehydration include dry mouth, decreased frequency of urination, dark urine, headache, muscle weakness, or dizziness. Check with your doctor if you have any questions or concerns.

FOUNDAYO may lower your blood pressure and, together with fluid loss from vomiting or diarrhoea, may cause dizziness or fainting. Make sure you drink enough fluids and speak to your doctor if you feel faint or lightheaded.

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 FOUNDAYO and affect how it works. These medicines should be avoided.

Examples of medicines that may <u>increase</u> the effect of FOUNDAYO include:

- ritonavir - a medicine used to treat viral infections
- clarithromycin - an antibiotic used to treat bacterial infections
- itraconazole - an antifungal medicine used to treat fungal infections

Examples of medicines that may <u>reduce</u> the effect of FOUNDAYO include:

- carbamazepine - a medicine used to treat seizures and certain types of nerve pain
- bosentan - used to treat high blood pressure in the lungs (pulmonary arterial hypertension)
- efavirenz - an antiviral medicine used to treat HIV infection
- phenytoin - a medication used to control seizures (epilepsy)

- St John's wort (hypericum perforatum) - a herbal remedy often used for mild depression or mood disorders.

FOUNDAYO may affect how other medicines work including:

- simvastatin - a medication used to lower cholesterol levels in the blood.

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

4. How do I use FOUNDAYO?

How much to take

- **Starting Dose:** When you first start using FOUNDAYO, the starting dose is 0.8 mg once daily for 30 days.
- **Increasing Your Dose:** After 30 days, your doctor may increase your dose to 2.5 mg once a day.
- **Further Dose Increases:** If needed, your doctor may increase your dose every 30 days to achieve the desired effect. Possible doses include 5.5 mg, 9 mg, 14.5 mg or 17.2 mg once daily.
- **Maximum Dose:** The highest dose you may take is 17.2 mg once a day.
- **Important Reminders:**
  - Follow the instructions provided and use FOUNDAYO until your doctor tells you to stop.

- **Do not change your dose unless your doctor has told you to do so.**

When to take FOUNDAYO

- FOUNDAYO is taken once a day, at any time of day.
- Swallow the tablet whole with a glass of water. Do not chew, crush or split the tablet before swallowing.
- You can take the tablets either with or without food.

If you forget to use FOUNDAYO

FOUNDAYO should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as possible. Do not take more than one tablet per day.

If it is almost time for your next dose, just skip the one you missed and take your next dose at the usual time. Don't take extra medicine to make up for the missed dose.

If you use too much FOUNDAYO

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 FOUNDAYO?

Things you should do

- Tell your doctor or pharmacist if you are planning to travel overseas. You may not be able to get FOUNDAYO in the country you are visiting. Your doctor or pharmacist can provide you with some useful information.
- Remind any doctor, surgeon, anaesthetist, dentist, pharmacist or nurse you visit that you are using FOUNDAYO.

Testing blood glucose levels

If you are using FOUNDAYO with sulfonylurea or insulin (another diabetes medicine), it is important that you test your blood glucose levels as instructed by your doctor, nurse or pharmacist.

Call your doctor straight away if you:

- experience severe low blood sugar, called hypoglycaemia, and this worries you.

Things you should not do

- Do not take more than one tablet per day.

- Do not stop using this medicine suddenly and without consulting your healthcare provider.
- Do not use this medicine if the packaging is torn or shows signs of tampering.
- Do not give FOUNDAYO to anyone else, even if they have the same condition as you. Your doctor has prescribed FOUNDAYO only for you.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of certain side effects like low blood sugar (hypoglycaemia).

Looking after your medicine

- Store below 30°C.

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 windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

- If the expiry date on the carton has passed.
- If your doctor tells you to stop taking FOUNDAYO.

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.

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
Stomach-related: • feeling sick (nausea) • constipation • diarrhoea	**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
• vomiting - this usually goes away over time • abdominal (stomach) pain • indigestion (dyspepsia) - discomfort in the upper stomach • swelling or bloating of the stomach which may be painful (abdominal distension) • burping or belching • farting (flatulence) • heartburn (typically a burning sensation that begins just below the breastbone and moves up towards the throat) **General disorders:** • general feeling of tiredness (fatigue) • dizziness • changes in taste - food and drinks may taste different than usual **Skin- and hair-related:** • hair loss	

Less serious side effects	What to do
• tingling or strange skin sensations (dysaesthesia) - you could feel prickling, burning or numbness in your skin **Low blood sugar (hypoglycaemia) in patients with type 2 diabetes:** • If you take FOUNDAYO with other type 2 diabetes medicines, such as a sulfonylurea (e.g. gliclazide, glibenclamide, glipizide) or insulin, you may be at risk of low blood sugar. • Signs of low blood sugar can happen quickly and may include: sweating, pale skin, headache, shaking, fast heartbeat, nausea, hunger, blurred vision, dizziness, feeling weak or sleepy, mood changes, trouble concentrating, or unusual behaviour.	

Serious side effects

Serious side effects	What to do
Acute pancreatitis: Symptoms of inflamed pancreas (acute pancreatitis) may include: • severe pain in the stomach and back which does not go away; **and** • vomiting and/or diarrhoea **Severe low blood sugar levels (severe hypoglycaemia):** Symptoms of severe hypoglycaemia can include: • disorientation • seizures • unconsciousness **Heart-related:** • fast heartbeat or racing heart (tachycardia) **Vision-related:** • changes to, or loss of vision	**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
Gallbladder-related: • severe pain in right side; **and** • nausea and/or vomiting • fever	

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 FOUNDAYO contains

Active ingredient (main ingredient)	Orforglipron (as calcium)
Other ingredients (inactive ingredients)	**Tablet core content** copovidone crospovidone magnesium stearate microcrystalline cellulose sodium carbonate **Tablet film-coating** All strengths macrogol 4000 polyvinyl alcohol purified talc titanium dioxide 0.8 mg and 9 mg iron oxide red

	iron oxide yellow 2.5 mg and 14.5 mg iron oxide yellow 5.5 mg and 17.2 mg iron oxide black iron oxide red
Potential allergens	none

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

What FOUNDAYO looks like

FOUNDAYO 0.8 mg film-coated tablet

FOUNDAYO 0.8 mg tablet is a pink, round tablet debossed on one side with "G1" and debossed with "L" on the other side. The diameter of the tablet is approximately 6 mm. (AUST R 521939).

FOUNDAYO 2.5 mg film-coated tablet

FOUNDAYO 2.5 mg tablet is a light yellow, round tablet debossed on one side with "G2" and debossed with "L" on the other side. The diameter of the tablet is approximately 6 mm. (AUST R 521944).

FOUNDAYO 5.5 mg film-coated tablet

FOUNDAYO 5.5 mg tablet is a greyish purple, round tablet debossed on one side with "G3" and debossed with "L" on the other side. The diameter of the tablet is approximately 6 mm. (AUST R 521948).

FOUNDAYO 9 mg film-coated tablet

FOUNDAYO 9 mg tablet is a pink, oval shaped tablet debossed on one side with "G4" and debossed with “Lilly” on the other side. The tablet is approximately 10.3 mm x 5.0 mm. (AUST R 522875).

FOUNDAYO 14.5 mg film-coated tablet

FOUNDAYO 14.5 mg tablet is a light yellow, oval-shaped tablet debossed on one side with "G5" and debossed with "Lilly" on the other side. The tablet is approximately 11.9 mm x 5.7 mm. (AUST R 521941).

FOUNDAYO 17.2 mg film-coated tablet

FOUNDAYO 17.2 mg tablet is a greyish purple, oval-shaped tablet debossed on one side with "G6" and debossed with "Lilly" on the other side. The tablet is approximately 12.4 mm x 5.9 mm. (AUST R 521942).

Who distributes FOUNDAYO

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney, NSW 2000

Further information

If you have any questions about FOUNDAYO, contact Lilly at 1800 454 559 or your healthcare professional for assistance.

To check for CMI updates and obtain the latest version, visit www.ebs.tga.gov.au

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