

Package leaflet: Information for the patient

Foundayo[®] 0.8 mg film-coated tablets
Foundayo[®] 2.5 mg film-coated tablets
Foundayo[®] 5.5 mg film-coated tablets
Foundayo[®] 9 mg film-coated tablets
Foundayo[®] 14.5 mg film-coated tablets
Foundayo[®] 17.2 mg film-coated tablets
orforglipron



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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking 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, nurse or pharmacist.
- 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Foundayo is and what it is used for
2. What you need to know before you take Foundayo
3. How to take Foundayo
4. Possible side effects
5. How to store Foundayo
6. Contents of the pack and other information

1. What Foundayo is and what it is used for

Foundayo contains the active substance orforglipron and is used to treat adults with obesity or overweight. Foundayo influences appetite regulation, which may help you eat less food and reduce your body weight.

Foundayo is used together with a reduced-calorie diet and increased physical activity for weight loss and to help keep the weight under control in adults initially with:

- a BMI of 30 kg/m² or greater (obesity) or,
- a BMI of at least 27 kg/m² but less than 30 kg/m² (overweight) and at least one weight related health problem such as prediabetes, type 2 diabetes, high blood pressure, abnormal levels of fats in the blood, breathing problems during sleep called “obstructive sleep apnoea”, impaired heart function or a history of heart attack, stroke or blood vessel problems.

Foundayo is also used to treat adults with type 2 diabetes mellitus whose blood sugar is not properly controlled. Foundayo reduces the level of sugar in the body only when the levels of sugar are high.

Foundayo is used together with diet and exercise for the treatment of adults with type 2 diabetes:

- on its own, or
 - with other medicines for diabetes when they are not enough to control your blood sugar levels.
- These other medicines may be medicines taken by mouth or by injection such as insulin.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, nurse or pharmacist.

2. What you need to know before you take Foundayo

Do not take Foundayo

If you are allergic to orforglipron or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Foundayo if:

- You have or have ever had pancreatitis (inflammation of the pancreas which may cause severe pain in the stomach and back which does not go away; see section 4).
- You are using a sulfonylurea (another diabetes medicine) and/or insulin for your diabetes, as low blood sugar (hypoglycaemia) can occur. Your doctor may need to change your dose of these other medicines to reduce this risk.
- You have severe problems with food digestion or food remaining in your stomach for longer than normal (including severe gastroparesis).
- When starting treatment with Foundayo you may feel sick (nausea) or be sick (vomiting) or have diarrhoea. These side effects can cause dehydration (loss of fluids). It is important that you drink enough fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor, nurse or pharmacist if you have any questions or concerns.
- You are using antihypertensive medicines (for high blood pressure) as low blood pressure can occur. Your doctor may need to change your dose of these medicines to reduce this risk.
- You have gallbladder problems including symptoms such as pain in your upper stomach (abdomen), yellowing of skin or eyes (jaundice), clay-coloured stools or fever.
- You have a problem with your eyes or vision (diabetic retinopathy or macular oedema).
- You know that you are due to have surgery where you will be under anaesthesia (sleeping).
- You have or have had severe heart failure.

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.

Other medicines and Foundayo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some medicines may affect the way Foundayo works and Foundayo may affect the way other medicines work. For example, either medicine may become less effective or you may be more likely to experience side effects.

Some medicines may increase the concentration of Foundayo in your blood, such as

- clarithromycin (used to treat bacterial infections)
- itraconazole or ketoconazole (used to treat fungal infections)
- ritonavir or telaprevir (used to treat viral infections)

Some medicines may reduce the amount of Foundayo in your blood, such as

- carbamazepine (used to treat seizures or fits)
- bosentan (used to treat pulmonary hypertension)
- efavirenz (used to treat viral infections)
- rifampicin (used to treat bacterial infections)
- phenytoin (used to treat seizures)
- St. John's wort (*Hypericum perforatum*) (a herbal product used for depression and anxiety)

Foundayo may increase the amount of this medicine in your blood:

- simvastatin (for lowering cholesterol)
- rosuvastatin (for lowering cholesterol)
- topotecan (a treatment for certain types of cancers)

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This medicine should not be used during pregnancy as the effects of this medicine on an unborn child are not known. Therefore, it is recommended to use contraception while using this medicine. If you wish to become pregnant, discuss how to change your treatment with your doctor as you should stop using this medicine at least 3 weeks in advance.

Use of orforglipron may reduce the efficacy of oral hormonal contraceptives. If you are a woman using oral contraceptives, you should consider also using a barrier method of contraception (e.g., a condom) or switching to a non-oral contraceptive method for 30 days after starting Foundayo and for 30 days after each increase in dose.

Breast-feeding

It is unknown whether orforglipron passes into breast milk. A risk to newborns and infants cannot be ruled out. Foundayo should not be used during breast feeding.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive and use machines.

However, if you use Foundayo in combination with a sulfonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar, e.g. headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating (see section 4). See section 2, 'Warnings and precautions' for information on increased risk of low blood sugar. Talk to your doctor for further information.

Foundayo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Foundayo

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure how to take this medicine.

- The starting dose for Foundayo tablet is 0.8 mg once daily for 30 days. After 30 days your doctor should increase your dose to 2.5 mg once daily.
- After at least 30 days, your doctor can increase your dose to 5.5 mg once daily.
- After at least 30 days, your doctor may increase your dose to the next dose level (9 mg, 14.5 mg, and 17.2 mg) once daily if you need it. In each case your doctor will tell you to stay on a particular dose for at least 30 days before increasing to a higher dose.
- The maximum daily dose of Foundayo tablets is 17.2 mg daily.
- Do not change your dose unless your doctor has told you to.

You can take your once daily dose at any time of the day, with or without food.

Swallow the tablet whole. Do not break, crush or chew the tablet. Do not take more than one tablet per day.

Testing blood glucose levels

If you are taking Foundayo with a sulfonylurea and/or insulin, it is important that you test your blood glucose levels as instructed by your doctor, nurse or pharmacist (see section 2).

If you take more Foundayo than you should

If you take more Foundayo than you should talk to your doctor immediately. Too much of this medicine can make you feel sick or be sick.

If you forget to take Foundayo

If you forget to take a dose, take it as soon as you remember. Do not take more than one dose per day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Foundayo

Do not stop taking Foundayo without talking with your doctor. If you stop taking Foundayo, and you have type 2 diabetes, your blood sugar levels can increase.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects**Uncommon** (may affect up to 1 in 100 people)

- Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. This is a serious, potentially life-threatening condition. You should see a doctor immediately if you experience such symptoms.

Frequency not known (frequency may not be estimated from the available data).

Some patients taking this type of medication have reported these effects.

- Any sudden changes in your vision or any other unusual visual symptoms. You should tell your doctor if you experience these effects.
- Bowel obstruction which could cause severe tummy pain, a swollen tummy, being sick (vomiting), or not being able to pass wind or open your bowels.
- Severe constipation.
- Serious allergic reactions (anaphylactic reactions). You should get immediate medical help and inform your doctor if you experience symptoms such as breathing problems, swelling of face and throat, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.
- The chance of food or liquid getting into your lungs may increase during surgery or other procedures.
- Kidney problems have been reported sometimes requiring treatment with a kidney machine (dialysis). Signs may include dehydration resulting from vomiting or diarrhoea.

Other side effects**Very common** (may affect more than 1 in 10 people)

- Feeling sick (nausea)
- Constipation
- Diarrhoea
- Being sick (vomiting)
- Indigestion (dyspepsia)
- Stomach (abdominal) pain

These side effects are usually not severe. Nausea, diarrhoea, and vomiting are most common when first starting orforglipron but decrease over time in most patients.

- Low blood sugar (hypoglycaemia) when orforglipron is used with insulin with or without metformin and/or sodium-glucose co-transporter 2 inhibitors (SGLT2i).

Your doctor may reduce your dose of insulin before you start using this medicine (see section 2).

The warning signs of low blood sugar may include headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating. Your doctor should tell you how to treat low blood sugar

Common (may affect up to 1 in 10 people)

- Low blood sugar (hypoglycaemia) when orforglipron is used with medicines that contain a sulfonylurea alone or combined with up to two additional diabetes medications for type 2 diabetes. Your doctor may reduce your dose of sulfonylurea before you start using this medicine (see section 2)
- Dizziness
- Headache
- Fast pulse
- Low blood pressure
- Bloating of the stomach
- Burping (eructation)
- Reflux or heartburn (also called gastro-oesophageal reflux disease – GORD) - a disease caused by stomach acid coming up into the tube from your stomach to your mouth
- Gas (flatulence)
- Gallstones
- Hair loss
- Feeling tired (fatigue)
- Increased levels of pancreatic enzymes (such as lipase and amylase) in blood

Uncommon (may affect up to 1 in 100 people)

- Low blood sugar (hypoglycaemia) when orforglipron is used without insulin or sulfonylurea.
- Unusual sense of taste reported
- Unpleasant and abnormal feeling when touched

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Foundayo

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 carton and blister after ‘EXP’. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. This medicine is light sensitive.

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 Foundayo tablets contain

The active substance in Foundayo is orforglipron. Six different strengths of tablets are available.

Foundayo 0.8 mg film-coated tablets: Each tablet contains 0.8 mg of orforglipron

Foundayo 2.5 mg film-coated tablets: Each tablet contains 2.5 mg of orforglipron
Foundayo 5.5 mg film-coated tablets: Each tablet contains 5.5 mg of orforglipron
Foundayo 9 mg film-coated tablets: Each tablet contains 9 mg of orforglipron
Foundayo 14.5 mg film-coated tablets: Each tablet contains 14.5 mg of orforglipron
Foundayo 17.2 mg film-coated tablets: Each tablet contains 17.2 mg of orforglipron

The other ingredients are:

Tablet core: microcrystalline cellulose, crospovidone, copovidone, sodium carbonate anhydrous, magnesium stearate;

Tablet film-coating: poly (vinyl alcohol), titanium dioxide, macrogol, talc, iron oxide red (E172) (in the 0.8 mg, 5.5 mg, 9 mg and 17.2 mg tablets), iron oxide yellow (E172) (in the 0.8 mg, 2.5 mg, 9 mg and 14.5 mg tablets), and iron oxide black (E172) (in the 5.5 mg and 17.2 mg tablets). See also section 2, “Foundayo contains sodium”.

What Foundayo looks like and contents of the pack

Foundayo 0.8 mg film-coated tablets are pink, round (approximately 6 mm in diameter), debossed with ‘G1’ on one side and ‘L’ on the other side.

Foundayo 2.5 mg film-coated tablets are light yellow, round (approximately 6 mm in diameter), debossed with ‘G2’ on one side and ‘L’ on the other side.

Foundayo 5.5 mg film-coated tablets are greyish purple, round (approximately 6 mm in diameter), debossed with ‘G3’ on one side and ‘L’ on the other side.

Foundayo 9 mg film-coated tablets are pink, modified oval shaped (approximately 10 mm x 5 mm), debossed with ‘G4’ on one side and ‘Lilly’ on the other side.

Foundayo 14.5 mg film-coated tablets are light yellow, modified oval shaped (approximately 12 mm x 6 mm), debossed with ‘G5’ on one side and ‘Lilly’ on the other side.

Foundayo 17.2 mg film-coated tablets are greyish purple, modified oval shaped (approximately 12 mm x 6 mm), debossed with ‘G6’ on one side and ‘Lilly’ on the other side.

Foundayo film-coated tablets are available in blister packs of 30 and 90 film-coated tablets.

Not all pack sizes may be marketed.

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Other formats

This leaflet is available in other formats. If you would like a copy of this leaflet in Braille, large print, audio or another format, please contact your local Lilly Affiliate.

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

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