

Package leaflet: Information for the patient
Elegafit (Tirzepatide) 30 mg Solution for injection in pre-filled pen
Elegafit (Tirzepatide) 60 mg Solution for injection in pre-filled pen

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

1. What Elegafit is and what it is used for

Elegafit contains an active substance called tirzepatide and is used to treat adults with type 2 diabetes mellitus. Elegafit reduces the level of sugar in the body only when the levels of sugar are high. Elegafit is also used to treat adults with obesity or overweight (with BMI of at least 27 kg/m²). Elegafit influences appetite regulation, which may help you eat less food and reduce your body weight.

In type 2 diabetes, Elegafit is used:

- on its own when you can't take metformin (another diabetes medicine).
- 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 and/or insulin given by injection.

Elegafit is also used together with diet and exercise for weight loss and to help keep the weight under control in adults, who have:

- 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 weight-related health problems (such as prediabetes, type 2 diabetes, high blood pressure, abnormal levels of fats in the blood, breathing problems during sleep called 'obstructive sleep apnoea' or a history of heart attack, stroke or blood vessel problems) BMI (Body Mass Index) is a measure of your weight in relation to your height. 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 use Elegafit

Do not use Elegafit

- if you are allergic to tirzepatide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Elegafit if:

- you have severe problems with food digestion or food remaining in your stomach for longer than normal (including severe gastroparesis).
- you have ever had pancreatitis (inflammation of the pancreas which may cause severe pain in the stomach and back which does not go away).
- you have a problem with your eyes (diabetic retinopathy or macular oedema).
- you are using a sulphonylurea (another diabetes medicine) 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.

When starting treatment with Elegafit, in some cases you may experience loss of fluids/dehydration, e.g. due to vomiting, nausea and/or diarrhoea, which may lead to a decrease in kidney function. It is important to avoid dehydration by drinking plenty of fluids. Contact your doctor if you have any questions or concerns.

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 Elegafit

Tell your doctor, nurse or pharmacist if you are using, have recently used or might use any other medicines.

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.

Breast-feeding

It is unknown whether tirzepatide passes into breast milk. A risk to newborns/infants cannot be ruled out. If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you should stop breast-feeding or delay using Elegafit.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive and use machines. However, if you use Elegafit in combination with a sulphonylurea 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.

Elegafit contains sodium

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

3. How to use Elegafit

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

How much to use

- The starting dose is 2.5mg once a week for four weeks. After four weeks your doctor will increase your dose to 5mg once a week.
- Your doctor may increase your dose by 2.5mg increments to 7.5mg, 10 mg, 12.5 mg or 15mg once a week if you need it. In each case your doctor will tell you to stay on a particular dose for at least 4 weeks before going to a higher dose.
Do not change your dose unless your doctor has told you to. You can inject a dose of Elegafit into 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, or 15mg.

Choosing when to use Elegafit

You can use Elegafit at any time of the day, with or without meals. You should use it on the same day each week if you can. To help you remember when to use Elegafit, you may wish to mark on a calendar the day of the week when you inject your first dose. If necessary, you can change the day of your weekly Elegafit injection, as long as it has been at least 3 days since your last injection. After selecting a new dosing day, continue with once-a-week dosing on that new day.

How to inject Elegafit

Always use Elegafit exactly as your doctor has told you. Before you begin using Elegafit, always read the "Instructions for Use" below carefully, and talk to your doctor, nurse or pharmacist if you are not sure about how to inject Elegafit correctly. Elegafit is injected under the skin (subcutaneous injection) of your stomach area (abdomen) or upper leg (thigh) or upper arm. You may need help from someone else if you want to inject in your upper arm. **Do not** inject Elegafit directly into a vein, as this will change its action. If you want to do so, you can use the same area of your body each week. But be sure to choose a different injection site within that area. If you also inject insulin choose a different injection site for that injection. If you are blind or visually impaired, you will need help from someone to make your injection.

Testing blood glucose levels

If you are using Elegafit with a sulphonylurea or insulin, it is important that you test your blood glucose levels as instructed by your doctor, nurse or pharmacist (see section 2, 'Warnings and precautions').

If you use more Elegafit than you should

If you use more Elegafit than you should talk to your doctor immediately. Too much of this medicine may cause low blood sugar (hypoglycaemia) and can make you feel sick or be sick.

If you forget to use Elegafit

If you forget to inject a dose and,

- it has been **4 days or less** since you should have used Elegafit, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.
- If it has been **more than 4 days** since you should have used Elegafit, skip the missed dose.

Then inject your next dose as usual on your scheduled day. Do not use a double dose to make up for a forgotten dose. The minimum time between two doses must be at least 3 days.

If you stop using Elegafit

Do not stop using Elegafit without talking with your doctor. If you stop using Elegafit, 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. You should see a doctor immediately if you experience such symptoms.

Rare (may affect up to 1 in 1000 people)

- Severe allergic reactions (e.g. anaphylactic reaction, angioedema). You should get immediate medical help and inform your doctor if you experience symptoms such as breathing problems, rapid swelling of the lips, tongue and/or throat with difficulty swallowing and a fast heartbeat.

Other side effects

Very common (may affect more than 1 in 10 people)

- Feeling sick (nausea)
- Diarrhoea

These side effects are usually not severe. They are most common when first starting tirzepatide but decrease over time in most patients.

- Low blood sugar (hypoglycaemia) is very common when tirzepatide is used with medicines that contain a sulphonylurea and/or insulin. If you are using a sulphonylurea or insulin for type 2 diabetes, the dose may need to be lowered while you use tirzepatide (see section 2, 'Warnings and precautions'). Symptoms of low blood sugar may include headache, drowsiness, 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 tirzepatide is used for type 2 diabetes with both metformin and a sodium-glucose co-transporter 2 inhibitor (another diabetes medicine)
- Allergic reaction (hypersensitivity) (e.g., rash, itching, and eczema)
- Dizziness reported in patients treated for weight management
- Low blood pressure reported in patients treated for weight management
- Feeling less hungry (decreased appetite) reported in patients treated for type 2 diabetes
- Stomach (abdominal) pain
- Being sick (vomiting) – this usually goes away over time
- Indigestion (dyspepsia)
- Constipation
- Bloating of the stomach
- Burping (eructation)

- Gas (flatulence)
- Reflux or heartburn (also called gastroesophageal reflux disease – GERD) - a disease caused by stomach acid coming up into the tube from your stomach to your mouth
- Hair loss reported in patients treated for weight management
- Feeling tired (fatigue)
- Injection site reactions (e.g. itching or redness)
- Fast pulse
- 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 tirzepatide is used with metformin for type 2 diabetes.
- Gallstones
- Inflammation of the gallbladder
- Weight loss reported in patients treated for type 2 diabetes
- Injection site pain
- Increased calcitonin levels in blood.

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 via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Elegafit

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 vial label and on the carton after EXP. The expiry date refers to the last day of that month. Store in a refrigerator (2°C – 8°C). Do not freeze. If the vial has been frozen, DO NOT USE. Store in the original packaging in order to protect from light. Elegafit can be stored unrefrigerated below 30°C for up to 21 cumulative days and then the vial must be discarded. Do not use this medicine if you notice that the vial, seal or stopper is damaged, or the medicine is cloudy, discoloured or has particles in it. 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 Elegafit contains

The active substance is tirzepatide.

The other ingredients are disodium hydrogen phosphate heptahydrate (E339), sodium chloride, sodium hydroxide (see section 2 under 'Elegafit contains sodium' for further information); concentrated hydrochloric acid and water for injections.

What Elegafit looks like and contents of the pack

Elegafit is a clear, colourless to slightly yellow, solution for injection in a pre-filled pen. Each pre-filled contains 3 ml or 1.5 ml solution.

Instructions on how to use Elegafit 15 mg solution for injection in pre-filled pen

Please read these instructions carefully before using your Elegafit pre-filled pen.

Talk to your doctor, nurse or pharmacist about how to inject Elegafit correctly.

Start by checking your pen to make sure that it contains Elegafit 15 mg, then look at the illustrations below to get to know the different parts of your pen and needle.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help.

Get help from a person with good eyesight who knows how to use the Elegafit pre-filled pen. Your pen is a pre-filled dial-a-dose pen. It contains 4mg of semaglutide, and you can only select doses of 15 mg. One unused pen contains four doses of 15 mg.

Use the table inside the lid of the carton to keep track of how many injections you have taken and when you took the injections.

Your pen is designed to be used with 30G, 31G, and 32G disposable needles up to a length of 8mm.

Elegafit pre-filled pen and needle (example)

Pen cap

Outer needle cap

Inner needle cap

Needle

Paper tab

Pen window

Pen label

Dose counter

Dose pointer

Dose selector

Dose button

Flow check symbol

Important information

Pay special attention to these notes, as they are important for safe use of the pen.

1. Prepare your pen with a new needle

- Check the name and coloured label of your pen, to make sure that it contains Elegafit 15 mg. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- Pull off the pen cap.

• Check that the solution in your pen is clear and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.

• Take a new needle. Check the paper tab and the outer needle cap for damages that could affect sterility. If any damage is seen use a new needle.

• Tear off the paper tab.

Make sure to attach the needle correctly.

- Push the needle straight onto the pen.
- Turn until it is on tight.

The needle is covered by two caps. You must remove both caps. If you forget to remove both caps, you will not inject any solution.

• Pull off the outer needle cap and keep it for later. You will need it after the injection, to safely remove the needle from the pen.

• Pull off the inner needle cap and throw it away. If you try to put it back on, you may accidentally stick yourself with the needle.

A drop of solution may appear at the needle tip. This is normal, but you must still check the flow, if you use a new pen for the first time. See step 2 'Check the flow with each new pen'. Do not attach a new needle to your pen until you are ready to take your injection.

△ Always use a new needle for each injection. This may prevent blocked needles, contamination, infection and inaccurate dosing.

△ Never use a bent or damaged needle.

2. Check the flow with each new pen

- If your pen is already in use, go to step 3 'Select your dose'. Only check the flow before your first injection with each new pen.

• Turn the dose selector to the flow check symbol (→ → right past '0'. Make sure the flow check symbol lines up with the pointer.

• Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to '0'. The '0' must line up with the dose pointer. A drop of solution should appear at the needle tip.

A small drop may remain at the needle tip, but it will not be injected. If no drop appears, repeat step 2 'Check the flow with each new pen' up to 6 times. If there is still no drop, change the needle and repeat step 2 'Check the flow with each new pen' once more. Dispose of the pen and use new one if a drop of solution still does not appear.

△ Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that the solution flows. If no drop appears, you will not inject any medicine, even though the dose counter may move. This may indicate a blocked or damaged needle. If you do not check the flow before your first injection with each new pen, you may not get the prescribed dose and the intended effect of Elegafit.

3. Select your dose

- Turn the dose selector to select 15 mg. Keep turning until the dose counter stops and shows 15mg.

Only the dose counter and dose pointer will show that 15mg has been selected. You can only select 15mg per dose. When your pen contains less than 15mg, the dose counter stops before 1 is shown. The dose selector clicks differently when turned forwards, backwards or past 15mg. Do not count the pen clicks.

△ Always use the dose counter and the dose pointer to see that 15mg has been selected before injecting this medicine.

△ Do not count the pen clicks

△ Only doses of 15 mg must be selected with the dose selector. 15mg must line up precisely with the dose pointer to ensure that you get a correct dose.

How much solution is left

- To see how much solution is left, use the dose counter: Turn the dose selector until the dose counter stops. If it shows 15, at least 15mg is left in your pen. If the dose counter stops before 15mg, there is not enough solution left for a full dose of 15mg.

△ If there is not enough solution left in your pen for a full dose, do not use it. Use a new Elegafit pen.

4. Inject your dose

- Insert the needle into your skin as your doctor or nurse has shown you.
- Make sure you can see the dose counter. Do not cover it with your fingers. This could interrupt the injection.

Press and hold down the dose button. Watch as the dose counter returns to '0'. The '0' must line up with the dose pointer. You may then hear or feel a click.

• Continue pressing the dose button while keeping the needle in your skin.

• Count slowly to 6, while keeping the dose button pressed.

- If the needle is removed earlier, you may see a stream of solution coming from the needle tip. If so, the full dose will not be delivered.

• Remove the needle from your skin. You can then release the dose button. If blood appears at the injection site, press lightly.

You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.

△ Always watch the dose counter to know how many mg you inject. Hold the dose button down until the dose counter returns to '0'.

How to identify a blocked or damaged needle

- If '0' does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- In this case, you have not received any medicine – even though the dose counter has moved from the original dose that you have set.

How to handle a blocked needle

Change the needle as described in step 5 'After your injection' and repeat all steps starting with step 1 'Prepare your pen with a new needle'. Make sure you select the full dose you need. **Never touch the dose counter when you inject.** This can interrupt the injection.

5. After your injection

Always dispose of the needle after each injection to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will not inject any medicine.

- Lead the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap.

- Once the needle is covered, carefully push the outer needle cap completely on.
- Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist or local authorities.

Put the pen cap on your pen after each use to protect the solution from light.

When the pen is empty, throw it away without a needle on as instructed by your doctor, nurse, pharmacist or local authorities.

△ Never try to put the inner needle cap back on the needle. You may stick yourself with the needle. Always remove the needle from your pen immediately after each injection.

△ This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.

△ Further important information

- Always keep your pen and needles out of the sight and reach of others, especially children.
- Never share your pen or your needles with other people.
- Caregivers must be very careful when handling used needles to prevent needle injury and cross-infection.

Caring for your pen

Treat your pen with care. Rough handling or misuse may cause inaccurate dosing. If this happens you might not get the intended effect of this medicine.

- Do not leave the pen in a car or another place where it can get too hot or too cold.
- Do not inject Elegafit which has been frozen. If you do that, you might not get the intended effect of this medicine.
- Do not inject Elegafit which has been exposed to direct sunlight. If you do that, you might not get the intended effect of this medicine.
- Do not expose your pen to dust, dirt or liquid.
- Do not wash, soak or lubricate your pen. It may be cleaned with a mild detergent on a moistened cloth.
- Do not drop your pen or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the flow before you inject.
- Do not try to refill your pen. Once empty, it must be disposed of.
- Do not try to repair your pen or pull it apart.

Elegafit Clicks Dosage's

1	Click	=	0.2 mg
2	Clicks	=	0.4 mg
3	Clicks	=	0.6 mg
4	Clicks	=	0.8 mg
5	Clicks	=	1.0 mg
6	Clicks	=	1.2 mg
7	Clicks	=	1.4 mg
8	Clicks	=	1.6 mg
9	Clicks	=	1.8 mg
10	Clicks	=	2.0 mg
11	Clicks	=	2.2 mg
12	Clicks	=	2.4 mg
13	Clicks	=	2.6 mg
14	Clicks	=	2.8 mg
15	Clicks	=	3.0 mg
16	Clicks	=	3.2 mg
17	Clicks	=	3.4 mg
18	Clicks	=	3.6 mg
19	Clicks	=	3.8 mg
20	Clicks	=	4.0 mg
21	Clicks	=	4.2 mg
22	Clicks	=	4.4 mg
23	Clicks	=	4.6 mg
24	Clicks	=	4.8 mg
25	Clicks	=	5.0 mg
26	Clicks	=	5.2 mg
27	Clicks	=	5.4 mg
28	Clicks	=	5.6 mg
29	Clicks	=	5.8 mg
30	Clicks	=	6.0 mg
31	Clicks	=	6.2 mg
32	Clicks	=	6.4 mg
33	Clicks	=	6.6 mg
34	Clicks	=	6.8 mg
35	Clicks	=	7.0 mg
36	Clicks	=	7.2 mg
37	Clicks	=	7.4 mg
38	Clicks	=	7.6 mg
39	Clicks	=	7.8 mg
40	Clicks	=	8.0 mg
41	Clicks	=	8.2 mg
42	Clicks	=	8.4 mg
43	Clicks	=	8.6 mg
44	Clicks	=	8.8 mg
45	Clicks	=	9.0 mg
46	Clicks	=	9.2 mg
47	Clicks	=	9.4 mg
48	Clicks	=	9.6 mg
49	Clicks	=	9.8 mg
50	Clicks	=	10.0 mg
51	Clicks	=	10.2 mg
52	Clicks	=	10.4 mg
53	Clicks	=	10.6 mg
54	Clicks	=	10.8 mg
55	Clicks	=	11.0 mg
56	Clicks	=	11.2 mg
57	Clicks	=	11.4 mg
58	Clicks	=	11.6 mg
59	Clicks	=	11.8 mg
60	Clicks	=	12.0 mg
61	Clicks	=	12.2 mg
62	Clicks	=	12.4 mg
63	Clicks	=	12.6 mg
64	Clicks	=	12.8 mg
65	Clicks	=	13.0 mg
66	Clicks	=	13.2 mg
67	Clicks	=	13.4 mg
68	Clicks	=	13.6 mg
69	Clicks	=	13.8 mg
70	Clicks	=	14.0 mg
71	Clicks	=	14.2 mg
72	Clicks	=	14.4 mg
73	Clicks	=	14.6 mg
74	Clicks	=	14.8 mg
75	Clicks	=	15.0 mg