

Package leaflet: Information for the patient

Elegafit 1mg solution for injection in pre-filled pen
semaglutide

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 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 nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is 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 the active substance semaglutide. It helps your body reduce your blood sugar level only when blood sugar is too high and can help prevent heart disease in patients with type 2 diabetes mellitus (T2DM). It also helps to slow down deterioration of kidney function in patients with T2DM by a mechanism beyond blood glucose lowering.

Elegafit is used to treat adults (aged 18 years and older) with T2DM when diet and exercise is not enough:

- on its own – when you cannot use metformin (another diabetes medicine) or
- with other medicines for diabetes – when they are not enough to control your blood sugar levels.
- These may be medicines you take by mouth or inject as insulin.

It is important that you continue with your diet and exercise plan as told by your doctor, pharmacist or nurse.

2. What you need to know before you use Elegafit

- **Do not use Elegafit**
- if you are allergic to semaglutide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using this medicine.

This medicine is not the same as insulin and you should not use it if:

- you have type 1 diabetes – a condition where your body does not produce any insulin
- you develop diabetic ketoacidosis – a complication of diabetes with high blood sugar, breathing difficulty, confusion, excessive thirst, a sweet smell to the breath or a sweet or metallic taste in the mouth.

Elegafit is not an insulin and should therefore not be used as a substitute for insulin. If you know that you are due to have surgery where you will be under anaesthesia (sleeping), please tell your doctor that you are taking Elegafit.

Effects on the digestive system

During treatment with this medicine , 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 plenty of fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.

Severe and on-going stomach pain which could be due to **acute pancreatitis**.

If you have severe and on-going pain in the stomach area – see a doctor straight away as this could be a sign of acute pancreatitis (inflamed pancreas). Please see section 4 for the warning signs of inflamed pancreas.

Low blood sugar (hypoglycaemia)

Combining a sulphonylurea or an insulin with this medicine might increase the risk of getting low blood sugar levels (hypoglycaemia). Please see section 4 for the warning signs of low blood sugar levels. Your doctor may ask you to test your blood sugar levels. This will help your doctor decide if the dose of the sulphonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Diabetic eye disease (retinopathy)

If you have diabetic eye disease and are using insulin, this medicine may lead to a worsening of your vision, and this may require treatment. Tell your doctor if you have diabetic eye disease or if you experience eye problems during treatment with this medicine. In case you have potentially unstable diabetic eye disease, it is not recommended that you use Elegafit 2mg.

Children and adolescents

This medicine is not recommended in children and adolescents aged under 18 years as the safety and efficacy in this age group have not yet been established.

Other medicines and Elegafit

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including herbal medicines or other medicines you bought without a prescription. In particular, tell your doctor, pharmacist or nurse if you are using medicines containing any of the following:

- Warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). You may need frequent blood tests to check how quickly your blood clots.
- If you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend you to 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

If you are pregnant or breast-feeding, think you might be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. This medicine should not be used during pregnancy, as it is not known if it affects an unborn baby. Therefore, use of contraception is recommended while using this medicine. If you wish to become pregnant, discuss how to change your treatment with your doctors as you should stop using this medicine at least 2 months in advance. If you become pregnant while using this medicine, talk to your doctor right away, as your treatment will need to be changed. Do not use this medicine if you are breast-feeding, as it is unknown if it passes into breast milk.

Driving and using machines

Elegafit is unlikely to affect your ability to drive and use machines. If you use this medicine in combination with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may affect your ability to concentrate. Do not drive or use machines if you get any signs of low blood sugar. See section 2, 'Warnings and precautions' for information on increased risk of low blood sugar and section 4 for the warning signs of low blood sugar. Talk to your doctor for further information.

Sodium content

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 has told you. Check with your doctor, pharmacist or nurse if you are not sure.
- How much to use**
- The starting dose is 0.25 mg once a week for four weeks.
 - After four weeks your doctor will increase your dose to 0.5mg once a week.
 - Your doctor may increase your dose to 1mg once a week if your blood sugar is not controlled well enough with a dose of 0.5mg once a week.
 - Your doctor may increase your dose to 2mg once a week if your blood sugar is not controlled well enough with a dose of 1mg once a week.
- Do not change your dose unless your doctor has told you to.

How Elegafit is given

Elegafit is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

- The best places to give the injection are the front of your thighs, the front of your waist (abdomen), or your upper arm.
- Before you use the pen for the first time, your doctor or nurse will show you how to use it. Detailed instructions for use are on the other side of this package leaflet.

When to use Elegafit

- You should use this medicine 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 this medicine once a week only, it is recommended to note the chosen weekday (e.g. Wednesday) on the carton and to write the date on the carton every time you have injected it. If necessary you can change the day of your weekly injection of this medicine as long as it has been at least 3 days since your last injection of it. After selecting a new dosing day, continue with once a week dosing.

If you use more Elegafit than you should

If you use more Elegafit than you should, talk to your doctor straight away. You may get side effects such as feeling sick (nausea).

If you forget to use Elegafit

If you forgot to inject a dose and:

- it is 5 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.
- it is more than 5 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.

If you stop using Elegafit

Do not stop using this medicine without talking to your doctor. If you stop using it, your blood sugar levels may increase. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects

- **Common** (may affect up to 1 in 10 people)
- complications of diabetic eye disease (retinopathy) – you should tell your doctor if you get eye problems, such as changes in vision, during treatment with this medicine.
- **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 1 000 people)
- severe allergic reactions (anaphylactic reactions, angioedema). You must get immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face, lips, tongue and/or throat with difficulty swallowing and a fast heartbeat.
 - **Not known** (frequency cannot be estimated from the available data)
 - Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.

Other side effects

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

- feeling sick (nausea) – this usually goes away over time
- diarrhoea – this usually goes away over time
- low blood sugar (hypoglycaemia) when this medicine is used with medicines that contain a sulphonylurea or insulin.

Common (may affect up to 1 in 10 people)

- being sick (vomiting)
- low blood sugar (hypoglycaemia) when this medicine is used with oral diabetes medicine other than sulphonylurea or insulin

The warning signs of low blood sugar may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating or shaking. Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs. Low blood sugar is more likely to happen if you also take a sulphonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this medicine.

- indigestion
- inflamed stomach ("gastritis") – the signs include stomach ache, feeling sick (nausea) or being sick (vomiting)
- reflux or heartburn – also called 'gastro-esophageal reflux disease' (GERD)
- stomach pain
- bloating of the stomach
- constipation
- burping
- gall stones
- dizziness
- tiredness
- weight loss
- less appetite
- gas (flatulence)
- increase of pancreatic enzymes (such as lipase and amylase).

Uncommon (may affect up to 1 in 100 people)

- change in the way food or drink tastes
- fast pulse
- injection site reactions – such as bruising, pain, irritation, itching and rash
- allergic reactions like rash, itching or hives
- a delay in the emptying of the stomach.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Before opening:

Store in a refrigerator (2°C–8°C). Do not freeze. Keep away from the cooling element. Keep the pen cap on in order to protect from light.

- During use:**
- You can keep the pen for 6 weeks when stored at a temperature below 30°C in a refrigerator (2°C–8°C) away from the cooling element. Do not freeze Elegafit and do not use it if it has been frozen.
 - When you are not using the pen, keep the pen cap on in order to protect from light. Do not use this medicine if you notice that the solution is not clear and/or almost colourless. 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 semaglutide. One ml solution for injection contains 1.34mg semaglutide. One pre-filled pen contains 4mg semaglutide in 3ml solution. Each dose contains 1 mg of semaglutide in 0.75ml.
 - The other ingredients are: disodium phosphate dihydrate, propylene glycol, phenol, water for injections, sodium hydroxide/hydrochloric acid (for pH adjustment). See also section 2, 'Sodium content'.

What Elegafit looks like and contents of the pack

Elegafit is a clear and colourless or almost colourless solution for injection in a pre-filled pen. Each pre-filled pen contains 3ml solution, delivering 4 doses of 1 mg.

Instructions on how to use Elegafit 1 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 1mg**, 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 1mg. One unused pen contains four doses of 1mg.

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)

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 1 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 sight.

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 will 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 1 mg. Keep turning until the dose counter stops and shows 1mg.

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

Always use the dose counter and the dose pointer to see that 1mg has been selected before injecting this medicine.

Do not count the pen clicks

Only doses of 1 mg must be selected with the dose selector. 1mg 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 1, at least 1mg is left in your pen. If the dose counter stops before 1mg, there is not enough solution left for a full dose of 1mg.

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 in 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 | = | 0.01mg |
| 2 Clicks | = | 0.03mg |
| 3 Clicks | = | 0.04mg |
| 4 Clicks | = | 0.06mg |
| 5 Clicks | = | 0.07mg |
| 6 Clicks | = | 0.08mg |
| 7 Clicks | = | 0.10mg |
| 8 Clicks | = | 0.11mg |
| 9 Clicks | = | 0.13mg |
| 10 Clicks | = | 0.14mg |
| 11 Clicks | = | 0.15mg |
| 12 Clicks | = | 0.17mg |
| 13 Clicks | = | 0.18mg |
| 14 Clicks | = | 0.19mg |
| 15 Clicks | = | 0.21mg |
| 16 Clicks | = | 0.22mg |
| 17 Clicks | = | 0.24mg |
| 18 Clicks | = | 0.25mg |
| 19 Clicks | = | 0.26mg |
| 20 Clicks | = | 0.28mg |
| 21 Clicks | = | 0.29mg |
| 22 Clicks | = | 0.31mg |
| 23 Clicks | = | 0.32mg |
| 24 Clicks | = | 0.33mg |
| 25 Clicks | = | 0.35mg |
| 26 Clicks | = | 0.36mg |

- | | | |
|-----------|---|--------|
| 27 Clicks | = | 0.38mg |
| 28 Clicks | = | 0.39mg |
| 29 Clicks | = | 0.40mg |
| 30 Clicks | = | 0.42mg |
| 31 Clicks | = | 0.43mg |
| 32 Clicks | = | 0.44mg |
| 33 Clicks | = | 0.46mg |
| 34 Clicks | = | 0.47mg |
| 35 Clicks | = | 0.49mg |
| 36 Clicks | = | 0.50mg |
| 37 Clicks | = | 0.51mg |
| 38 Clicks | = | 0.53mg |
| 39 Clicks | = | 0.54mg |
| 40 Clicks | = | 0.56mg |
| 41 Clicks | = | 0.57mg |
| 42 Clicks | = | 0.60mg |
| 43 Clicks | = | 0.61mg |
| 44 Clicks | = | 0.63mg |
| 45 Clicks | = | 0.64mg |
| 46 Clicks | = | 0.64mg |
| 47 Clicks | = | 0.65mg |
| 48 Clicks | = | 0.67mg |
| 49 Clicks | = | 0.68mg |
| 50 Clicks | = | 0.69mg |
| 51 Clicks | = | 0.71mg |
| 52 Clicks | = | 0.72mg |
| 53 Clicks | = | 0.74mg |
| 54 Clicks | = | 0.75mg |
| 55 Clicks | = | 0.76mg |
| 56 Clicks | = | 0.78mg |
| 57 Clicks | = | 0.79mg |
| 58 Clicks | = | 0.81mg |
| 59 Clicks | = | 0.82mg |
| 60 Clicks | = | 0.83mg |
| 61 Clicks | = | 0.85mg |
| 62 Clicks | = | 0.86mg |
| 63 Clicks | = | 0.88mg |
| 64 Clicks | = | 0.89mg |
| 65 Clicks | = | 0.90mg |
| 66 Clicks | = | 0.92mg |
| 67 Clicks | = | 0.93mg |
| 68 Clicks | = | 0.94mg |
| 69 Clicks | = | 0.96mg |
| 70 Clicks | = | 0.97mg |
| 71 Clicks | = | 0.99mg |
| 72 Clicks | = | 1.0mg |