Novo-lela

Semaglutide

Cartridge and Auto-injector Pen

Package leaflet: Information for the patient
Semaglutide solution for injection in pre-mixed cartridge**.**

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 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 in this leaflet

1. What Semaglutide is and what it is used for?

What Semaglutide is

Semaglutide is a medicine for weight loss and weight maintenance that contains the active substance semaglutide. It is similar to a natural hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestine after a meal. Semaglutide works by acting on receptors in the brain that control your appetite, causing you to feel fuller and less hungry and experience less craving for food. This will help you eat less food and reduce your body weight. Semaglutide should be used with a reduced calorie meal plan and increased physical activity.

What Semaglutide is used for

Semaglutide is used for weight loss and weight maintenance in addition to diet and physical activity in adults, who have:

- a BMI of 30 kg/m² or greater (with obesity) or
- a BMI of 27 kg/m² and less than 30 kg/m² (overweight) and weight-related health problems.

BMI (Body Mass Index) is a measure of your weight in relation to your height.

2. What you need to know before you use Semaglutide?

Do not use Semaglutide 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 Semaglutide or during treatment if you have:

- **Effects on the digestive system**
  During treatment with Semaglutide, 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 if you have any questions or concerns.
- **Inflammation of the pancreas**
  If you have severe and on-going pain in the stomach area, see a doctor straight away as this could be a sign of inflamed pancreas (acute pancreatitis).
- **Diabetes**
  Semaglutide must not be used as a substitute for insulin.
- **Low blood sugar (hypoglycaemia)**
  Taking a sulfonylurea or an insulin with Semaglutide 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 sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.
- **Diabetic eye disease (retinopathy)**
  Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. If you have diabetic eye disease and experience eye problems while taking this medicine, talk to your doctor.

Children and adolescents
This medicine is not recommended in children and adolescents under 18 years as there is no information on use in children below this age.

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

Pregnancy and breast-feeding
This medicine should not be used during pregnancy, as it is not known if it may affect your unborn child. Therefore, it is recommended to use contraception while using this medicine. If you wish to become pregnant, you should stop using this medicine at least two months in advance. If you become or are pregnant, think you may be pregnant or are planning to have a baby when using this medicine, talk to your doctor straight away, as your treatment will need to be stopped.
You should not use this medicine if you are breast-feeding, as it is unknown if it passes into breast milk.

Driving and using machines
Semaglutide is unlikely to affect your ability to drive and use machines. Some patients may feel dizzy when taking Semaglutide mainly during the first 3 months of treatment (see section 4). If you feel dizzy you should not drive or operate machines until you feel better. If you need any further information, talk to your doctor, pharmacist or nurse.

For diabetics using this medicine in combination with a sulfonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Do not drive or use machines if you get any signs of low blood sugar. See section 2, 'Warning 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 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Semaglutide?

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 maximum recommended dose is 2.4 mg once weekly.

Your treatment will start at a low dose which will be gradually increased over 16 weeks of treatment as follows:

- When you first start using Semaglutide, the starting dose is 0.25 mg once weekly.
- Your doctor will instruct you to gradually increase your dose every 4 weeks until you reach the recommended dose of 2.4 mg once weekly.
- Once you reach the maximum recommended dose of 2.4 mg, do not increase this dose further.

DOSAGE AND INSTRUCTIONS:

CATRIDGE AND INSULIN SYRINGE

Semaglutide 4mg/3ml - Cartridge and Insulin Syringe			
	Dose escalation	**Weekly dose**	**Units to inject via insulin syringe**
Starting Weeks	Week 1–4	0.25 mg	18 units
Loading Phase 1	Week 5–8	0.5 mg	38 units
Loading Phase 2	Week 9–12	1 mg	75 units
Loading Phase 3*	Week 13–16	1.7 mg	64 units Monday, 64 units Thursday
Maintenance	From week 17	2.4 mg	90 units Monday, 90 units Thursday
***NOTE:** *Phase 3 - Week 13: It is recommended to switch to the Semaglutide 12mg/3ml for easier dosage*.*			

Semaglutide 12mg/3ml - Cartridge and Insulin Syringe			
	Dose escalation	**Weekly dose**	**Units to inject**
Starting Weeks	Week 1–4	0.25 mg	6 units
Loading Phase 1	Week 5–8	0.5 mg	13 units
Loading Phase 2	Week 9–12	1 mg	25 units
Loading Phase 3	Week 13–16	1.7 mg	43 units
Maintenance	From week 17	2.4 mg	60 units

AUTO-INJECTOR PEN

Semaglutide 4mg/3ml Auto-injector Pen			
	Dose escalation	**Weekly dose**	**Units to inject via Auto-injector Pen**
Starting Weeks	Week 1–4	0.25 mg	18 clicks on the pen
Loading Phase 1	Week 5–8	0.5 mg	38 clicks on the pen
Loading Phase 2	Week 9–12	1 mg	75 clicks on the pen
Loading Phase 3	Week 13–16	1.7 mg	64 clicks on the pen 2x per week (EG: Mon, Thurs)
Maintenance	From week 17	2.4 mg	90 clicks on the pen 2x per week (EG: Mon, Thurs)
***NOTE:** *Phase 3 - Week 13: It is recommended to switch to the Semaglutide 12mg/3ml for easier dosage*.*			

Semaglutide 12mg/3ml Auto-injector Pen			
	Dose escalation	**Weekly dose**	**Units to inject via Auto-injector Pen**
Starting Weeks	Week 1–4	0.25 mg	6 clicks on the pen
Loading Phase 1	Week 5–8	0.5 mg	13 clicks on the pen
Loading Phase 2	Week 9–12	1 mg	25 clicks on the pen
Loading Phase 3	Week 13–16	1.7 mg	43 clicks on the pen
Maintenance	From week 17	2.4 mg	60 clicks on the pen

Your doctor will assess your treatment on a regular basis.

How Semaglutide is administered

Semaglutide 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 upper arms, stomach or upper legs.
- Before you use the pen for the first time, ask your doctor or nurse how to use it.

People with diabetes

Tell your doctor if you have diabetes. Your doctor may adjust the dose of your diabetes medicines to prevent you from getting low blood sugar.

- Do not mix Semaglutide up with other medicines that you inject (e.g. insulins).
- Do not use Semaglutide in combination with other medicines that contain GLP-1 receptor agonists (such as liraglutide, dulaglutide, exenatide or lixisenatide).

When to use Semaglutide

- You should use this medicine once a week and if possible, on the same day each week.
- You can give yourself the injection at any time of the day – regardless of meals.

If necessary, you can change the day of your weekly injection of this medicine if it has been at least 3 days since your last injection. After selecting a new dosing day, continue with once-a-week dosing.

If you use more Semaglutide than you should

Talk to your doctor straight away. You may get side effects such as feeling sick (nausea).

If you forget to use Semaglutide

If you forgot to inject a dose and:

- it is 5 days or less since you should have used Semaglutide, 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 Semaglutide, skip the missed dose. Then inject your next dose as usual on your next scheduled day. Do not take a double dose to make up for a forgotten dose.

If you stop using Semaglutide

Do not stop using this medicine without talking to your doctor. 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 (diabetic retinopathy). If you have diabetes, you should inform your doctor if you experience 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). Signs of inflamed pancreas may include severe and long-lasting pain in your stomach, the pain may move to your back. You should see your doctor **immediately** if you experience such symptoms.

Rare: may affect up to 1 in 1,000 people

- Severe allergic reactions (anaphylactic reactions, angioedema). <u>You should seek immediate medical help</u> 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, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.

Other side effects

Very common: may affect more than 1 in 10 people

- headache
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- constipation
- stomach pain
- feeling weak or tired.

These usually go away over time.

Common: may affect up to 1 in 10 people

- feeling dizzy
- upset stomach or indigestion
- burping
- gas (flatulence)

- bloating of the stomach
- inflamed stomach ('gastritis') – the signs include stomach-ache, feeling sick (nausea) or being sick (vomiting)
- reflux or heartburn – also called 'gastro-oesophageal reflux disease'
- gallstones
- hair loss
- injection site reactions
- low blood sugar (hypoglycaemia) in patients with diabetes.

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 sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this medicine.

Uncommon: may affect up to 1 in 100 people
- fast heartbeat
- increase of pancreatic enzymes (such as lipase and amylase) shown in blood tests.

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 Yellow Card Scheme at: 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 Semaglutide?

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.
Do not freeze Semaglutide and do not use it if it has been frozen.
Keep the pen cap on to protect from light.

Before opening:

Store in a refrigerator (2°C to 8°C). Keep away from the cooling element.

During use:
You can keep the pen for 6 weeks when stored at a temperature below 30°C or in a refrigerator (2°C to 8°C) away from cooling element.
Do not use this medicine if you notice that the solution is not clear and 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 Semaglutide contains

- The active substance is Semaglutide.
- The other ingredients are disodium phosphate dihydrate, propylene glycol, phenol, sodium hydroxide/hydrochloric acid (for pH adjustment), water for injection.

Semaglutide 4 mg pre-mixed cartridge solution for injection

One mL of solution contains 1.34 mg of Semaglutide. One pre-mixed cartridge contains 4.0 mg Semaglutide in 3 mL solution.

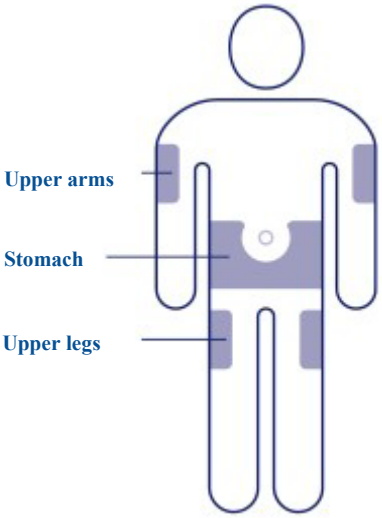
Semaglutide 12 mg pre-mixed cartridge solution for injection

One mL of solution contains 4 mg of Semaglutide. One pre-mixed cartridge contains 12.0 mg Semaglutide in 3 mL solution.

Dosage and directions for use of Semaglutide

Before you begin using your once-weekly injection of Semaglutide, **always read these instructions carefully,** and talk to your doctor, nurse or pharmacist about how to inject. **Semaglutide** correctly. Semaglutide should be used at prescribed dosages taken once a week for 4 weeks thereafter the next prescribed dosage should be administered.

Choose your injection site, inject subcutaneous only. Choose upper arms, stomach or upper legs (keep a 5 cm distance from your belly button).



You may inject in the same body area each week, but make sure it is not in the same spot as used the last time.

- If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks.
- The maintenance dose of SEMAGLUTIDE is 2.4 mg injected subcutaneously once-weekly.
- If patients do not tolerate the maintenance 2.4 mg once-weekly dose, the dose can be temporarily decreased to 1.7 mg once-weekly, for a maximum of 4 weeks. After 4 weeks, increase SEMAGLUTIDE to the maintenance 2.4 mg once-weekly.
  Discontinue SEMAGLUTIDE if the patient cannot tolerate the 2.4 mg dose.
- In patients with type 2 diabetes, monitor blood glucose prior to starting SEMAGLUTIDE and during SEMAGLUTIDE treatment.

What Semaglutide looks like and contents of the pack?

Semaglutide is a clear and colourless solution for injection in a pre-filled cartridge.

Semaglutide is a clear and colourless solution for injection in a pre-filled dispensing Auto-injector Pen .

Instructions for use of the Auto-injector Pen

Before you start using the Novo-lela® one-single injection pen please read these instructions carefully and consult your doctor.

The Auto-injector Pen is designed for use with single-use needles, Novo-lela® is compatible with any injection pens needles.

The package contains:
• Novo-lela® injection pen (Fig. 1)
• 4 needles (depending on the package, purchased separately if not available)
• Package insert scan QR code
• Patient information

Example of a Novo-lela® Auto injection pen

Please note that the size and color of the label on the syringe pen may differ from the sample shown in these pictures.

These instructions apply to all Novo-lela® Auto injection pens. (Fig. 1).

Fig. 1

1. Before use

Take the pen from the refrigerator. After removing from the refrigerator, keep the pen at room temperature for at least 30 minutes before use.

Check the label and expiration date to ensure that the product is suitable for use (Fig. 2).

Fig. 2

Remove the cap and check the presence of the medicine through the window. Make sure that the Novo-lela® in the injection pen is transparent, colourless or with a slightly brownish tint (Fig. 3).

Fig. 3

2. Preparing and inserting the needle

Take a new pen needle, remove the protective sticker (Fig. 4).

• Before removing the protective sticker, make sure that the protective sticker and the cap on the needle are completely closed, avoid using non-sterile needles.

• You should use a new needle, as needles are disposable and cannot be reused. Reuse can lead to infection and the inability to administer the required dose of the drug.

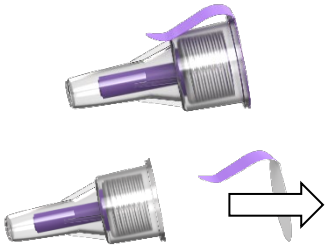


Fig.4

Align the outer needle cap with the pen and install it as shown in (Fig. 5).

Fig.5

Align the outer cap of the needle with the bottom towards the thread of the syringe pen and screw the needle directly onto the cartridge holder (Fig. 6, 7).

Fig.6 Fig.7

Remove the outer and then the inner needle caps (Fig. 8)

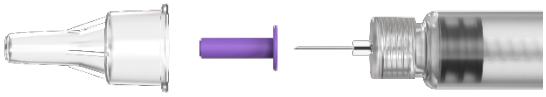


Fig.8

- Keep the outer needle cap so that it can be used after the injection.
- Discard the inner needle cap so that children do not eat it by mistake.
- Do not close the inner needle cap again to avoid accidental needle stick.

3. Removing air from the needle and checking its passableness

Turn the dose selector on the pen until the "□" symbol appears in the dose counter window and align it with the pointer (Fig. 9).

Fig 9

Hold the pen with the needle pointing upward, then press the trigger button until “0” appears in the dose counter window (Fig. 10, 11).

Fig.10

Fig. 11

Check if there are any drops on the tip of the needle. If there are no drops, repeat the air removal steps until drops appear on the tip of the needle (Fig. 12, 13).

Fig.12

Fig.13

- If drops do not appear after the air has been removed three times, it is possible that the needle of the syringe pen you are using is blocked. You should throw away this needle, replace it with a new one and repeat the steps described in point 3.
- It is permissible for there to be an air bubble in the drug solution visible in the window. This does not prevent the drug from being administered.

4. Injections

Select the site where you want to give the injection according to Fig. 15 and remove any clothing from the injection site.

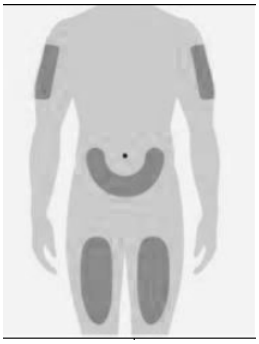


Fig.15

Insert the needle using the injection technique recommended by your doctor. Press the trigger button of the syringe pen (Fig. 16, 17).

Fig. 16

Fig. 17

Count 6-8 seconds after the dose counter window on the scale shows “0”. Then release the trigger button of the syringe pen and remove the needle from the skin (Fig. 18).

Fig. 18

- Removing the needle too early may prevent you from receiving the full dose of medication.
- Do not release the pen trigger until the dose indicator shows “0”. If the dose counter stops before the zero mark aligns with the pointer, this means that you have not received the required dose of medication.
- Please do not rely on the clicking sound to determine whether the injection is complete.

5. After injections

Place the outer needle cap on the table, then align the tip of the needle with the outer needle cap and insert it (Fig. 19).

Fig. 19

Once the needle enters the outer cap, gently push down on the outer cap until the needle is fully seated (Fig. 20, 21).

Fig.20

Fig. 21

Once the needle has entered the outer cap, gently press down on the outer cap until the needle is completely locked in place (Fig. 20, 21).

Fig. 22

Put the cap back on the pen and store it in a place protected from light (Fig. 23).

Fig. 23

- Remove the needle immediately after injection.
- Needles should be disposed of in accordance with the recommendations of health workers and sanitary and epidemiological standards.

WARNINGS:

- Do not freeze the pen.
- Avoid dropping the pen as it can break the inner cartridge and affect solutions stability.
- Do not place the pen in a high temperature or liquid environment.
- Do not attempt to refill the pen.
- Do not attempt to repair the pen.

Marketing Authorisation Holder and Manufacturer

Novo-lela
Product of Sweden
Marketed by: Novo-lela
www.novo-lela.com

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