

Getting Started with

Nevo^{lat}

(liraglutide)



This leaflet is not designed to replace the Package Leaflet that you will find inside the carton with your medicine. Please read the Package Leaflet carefully before injecting.

ZENTIVA

Your Medication



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The name of your new medicine is Nevolat[®], or liraglutide.

Liraglutide is a GLP1-RA (glucagon-like peptide-1 receptor agonist) that helps people lose weight, when they also exercise regularly and eat healthy foods.

Losing weight can have many benefits for your overall health.

How Nevolat works

Nevolat® is a weight loss medicine. It is similar to a natural hormone in our bodies called glucagon-like peptide-1 (GLP-1), which is released from the gut after a meal and tells us we're no longer hungry.

When you take Nevolat® medicine, it helps control your appetite by making you feel fuller and less hungry. It also slows down how quickly your stomach empties, so you stay full for longer.

Your doctor will start you on a diet and exercise programme.

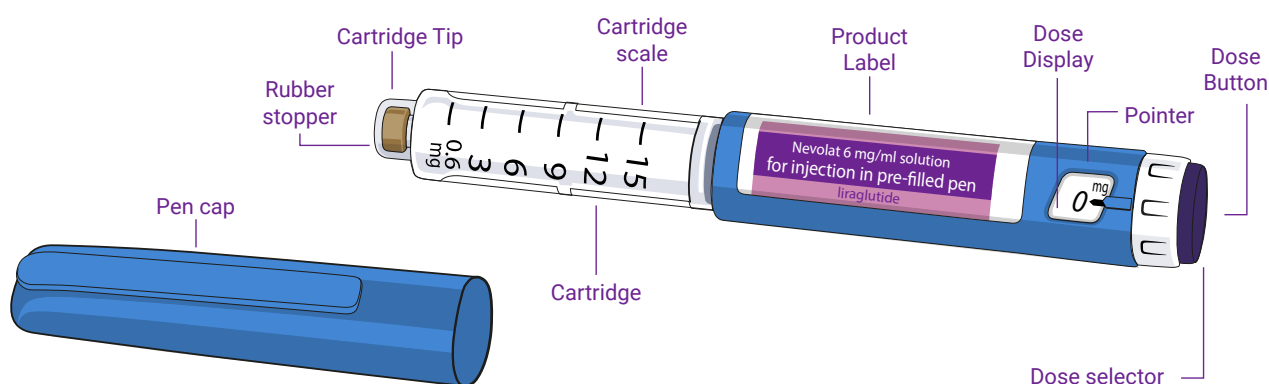
It is important to stay on this programme while you are using Nevolat® weight loss treatment plan.



The Nevolat Pen

Before you use the pen for the first time, your doctor or nurse will show you how to use the pre-filled pen, and the correct needles to use.

The pen is made up of the following parts:



Nevolat® pre-filled pens contain 18 mg of liraglutide. You can choose doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg.

The pen is designed to be used with disposable needles, which are not included in the pack. Speak to your doctor or nurse to ensure you have the correct needles to use. They will also provide you with a special bin (a 'sharps' bin) for safe needle disposal.

Top tips for safe use of the Nevolat[®] pen

It's important to use the Nevolat[®] pen safely to keep the medicine secure and avoid harming yourself.

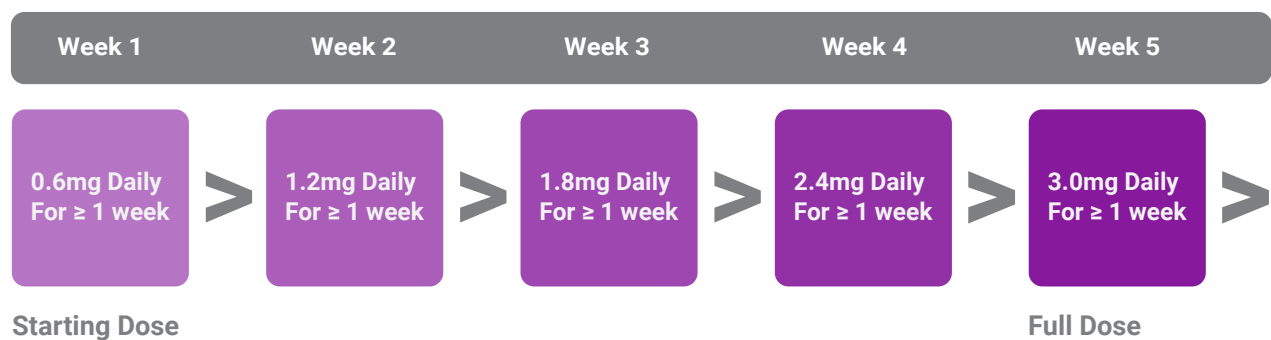
Here are some top tips to help you safely use the pen:

- To avoid potential infection, do not share the pen with other people, even if the needle has been changed
- Always use a new needle for each injection to prevent contamination
- The needle should be removed after each injection and the pen should be stored without the needle attached. This reduces the risk of contamination, infection, medicine leakage, blocked needles and incorrect dosing
- Keep out of reach of children
- If you drop your Nevolat[®] pen, or damage the needle, it should carefully be replaced. If the pen is damaged, do not try to repair the pen or pull it apart
- Never put the inner needle cap back on the needle, this may result in needle-stick injuries
- Do not wash, soak or lubricate the pen, as this can harm it. If cleaning is needed, use a cloth dampened with a mild detergent
- Keep the pen away from dust, dirt and all kinds of liquid
- The Nevolat[®] pen can be used for up to 30 days after first use, as long as it is refrigerated or kept below 30 °C

How much Nevolat[®] to use

Your Nevolat[®] treatment will start at a low dose (0.6 mg), which will gradually increase over the first five weeks of use. Starting from Week 5 of treatment, you will be taking liraglutide at a dose of 3.0 mg every day.

This is the highest dose of Nevolat[®] that you will take during your treatment – do not increase the dose any further.



Always use this medicine exactly as your doctor has told you.

Check with your doctor, pharmacist or nurse if you have any questions about taking Nevolat[®].

How to use your Nevolat[®] Pen

There are four simple steps to using your Nevolat[®] Pen:

Prep

Flow

Dose

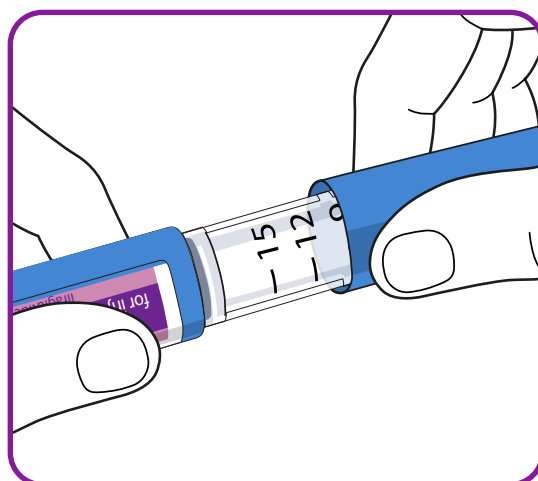
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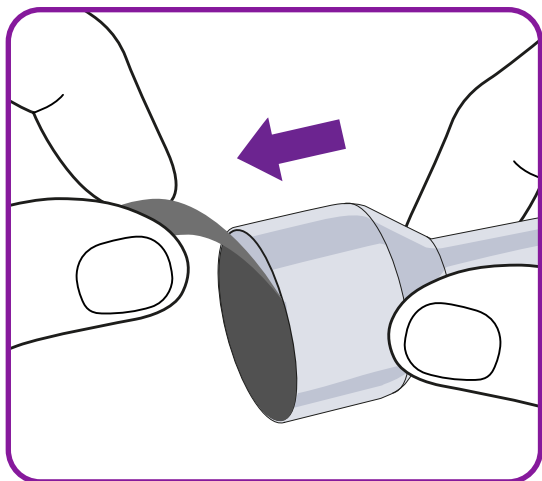
1. Prepare your pen with a new needle



Check the name and coloured label of the pen to ensure that it contains liraglutide. Using the wrong medicine could cause severe harm. Once checked, you can pull off the pen cap.

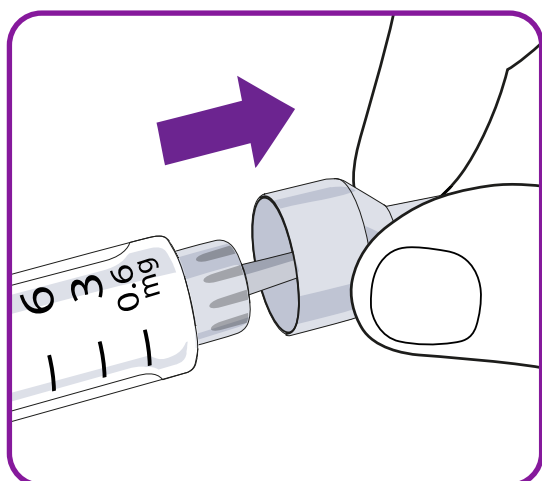
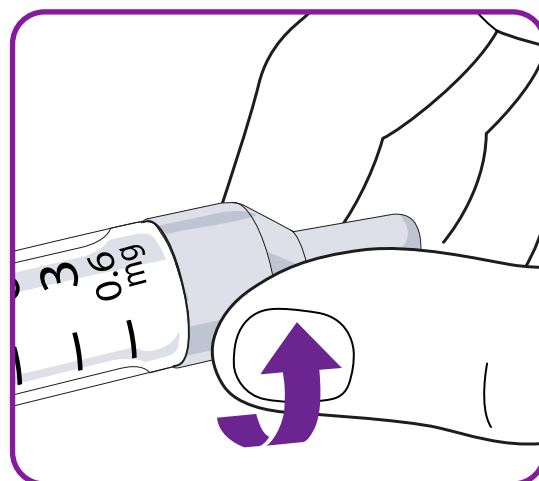
Check that the solution in the pen is clear and colourless by looking through the pen window. Do not use the pen if the solution looks cloudy.





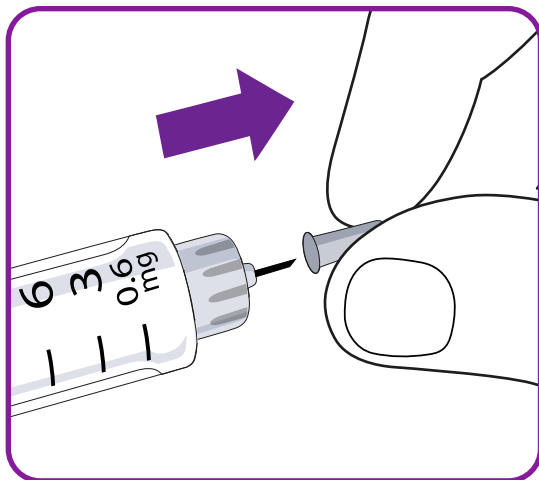
Remove the paper tab from a new disposable needle.

Screw the needle straight and tightly onto the pen.



The needle is covered by two caps.

Remove the outer needle cap and place on a clean surface for later.



Pull off the inner needle cap and throw it away. A drop of solution may appear at the needle tip. This is normal, but if you are using a new pen, you must still check the flow is working correctly. Do not attach a new needle to the pen until you are ready to have the injection.

2. Check the flow

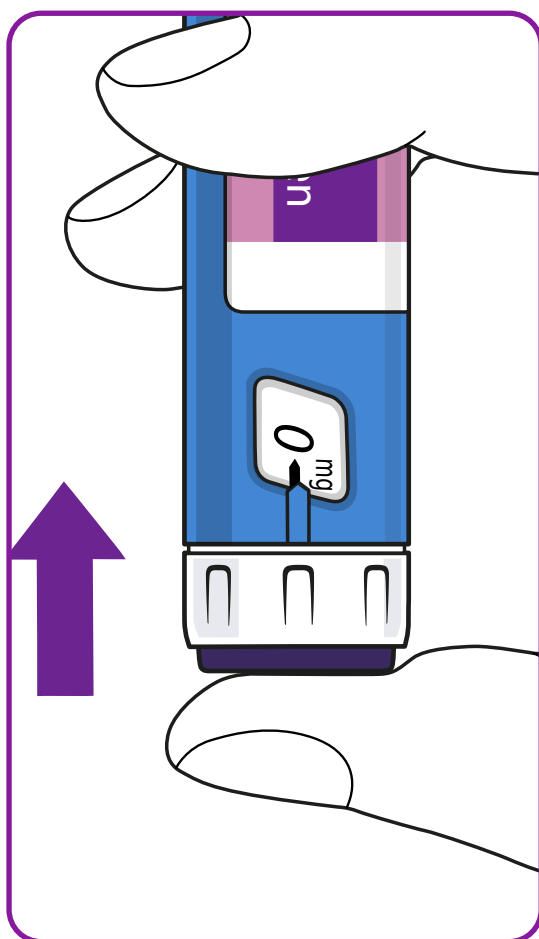
Check the flow with each new needle before injecting.

A new needle should be used with every injection to help prevent infections and blocked needles.

Turn the dose selector until the dose counter shows the flow check symbol right past 0.

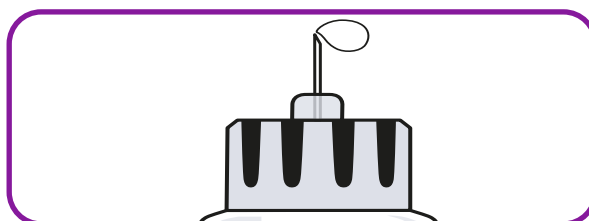
Hold the pen with the needle pointing up.





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.

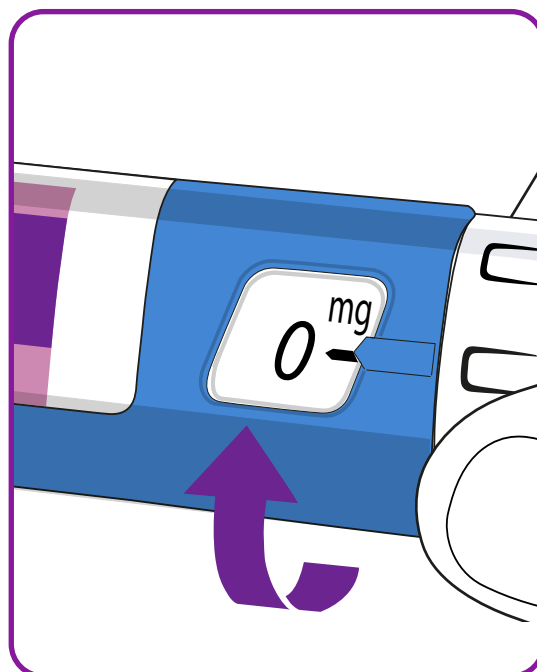
If no drop appears, you can repeat step 2 up to 6 times. If there is still no drop, the needle should be changed, and steps 1 and 2 repeated with a new pen.

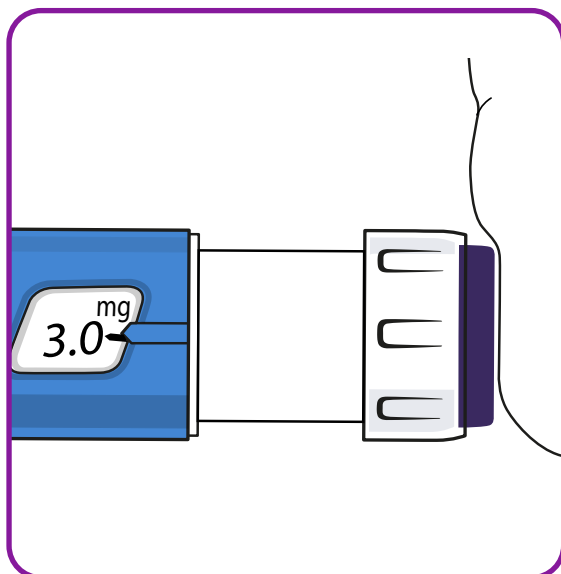


3. Selecting your dose

Turn the dose selector until the dose counter shows the dose that you need to take (0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg).

If the wrong dose is selected, the dose selector can be turned forwards or backwards to the correct setting. Only the dose counter and dose pointer will show how much medicine has been selected per dose.



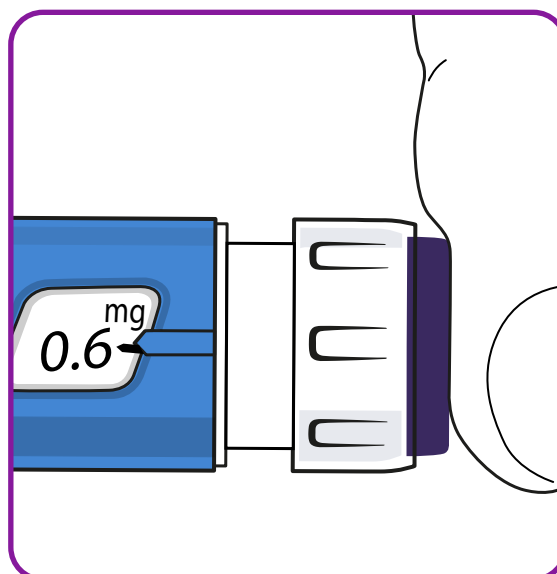


You should always use the dose counter and the dose pointer to see how much medicine you have selected before injecting this medicine. Only doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg must be selected with the dose selector. The selected dose must line up precisely with the dose pointer to ensure you get the correct dose.

Turn the dose selector until the dose counter stops.

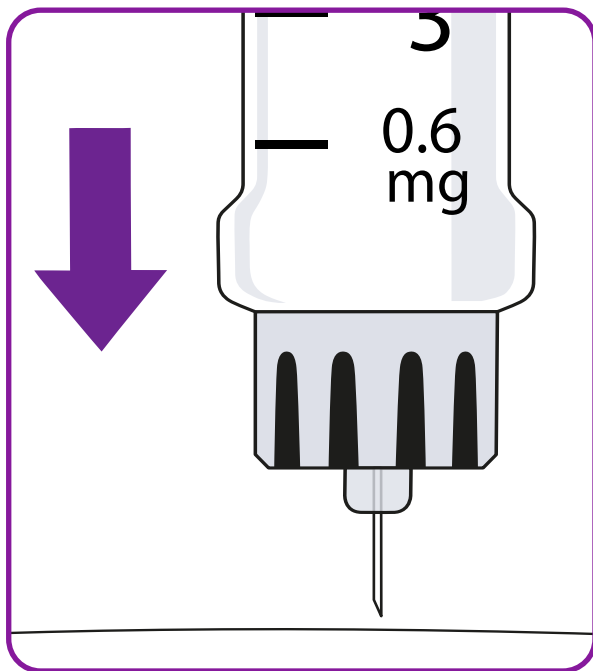
If the dose selector stops before the required dose lines up with the pointer there is not enough liraglutide left for a full dose. You may:

- Inject the full dose with a new pen
- Split your dose between the current pen and a new pen (only after discussing with your doctor or nurse)



Turn the dose selector in either direction until 0.6 mg or 1.2 mg lines up with the pointer, then inject the dose. Patients should then prepare a new pen for injection and inject the rest of the dose needed. A calculator may help you to plan the doses.

4. Injecting your medication

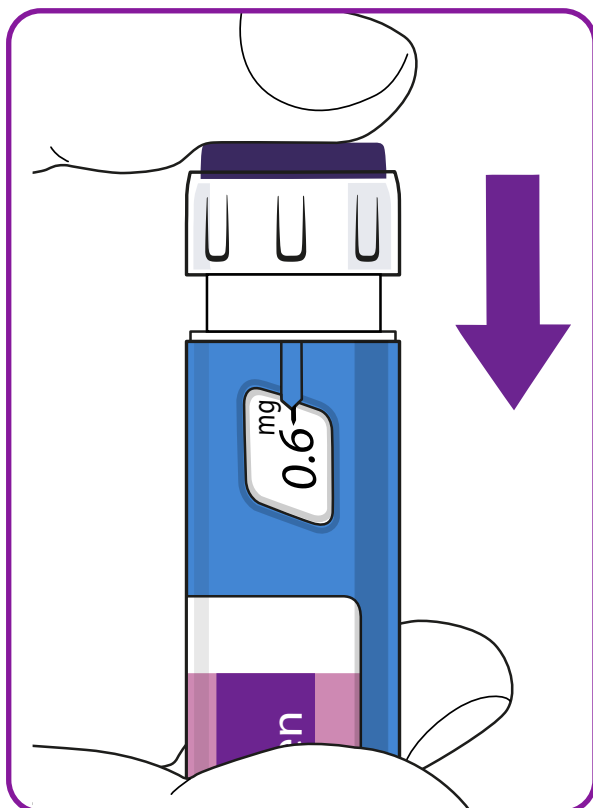


You should insert the needle into the skin as shown by your doctor or nurse:

Make sure you can see the dose counter. Try not to cover it with your fingers as this might interrupt the injection.

Press and hold down the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. You may then hear or feel a click.

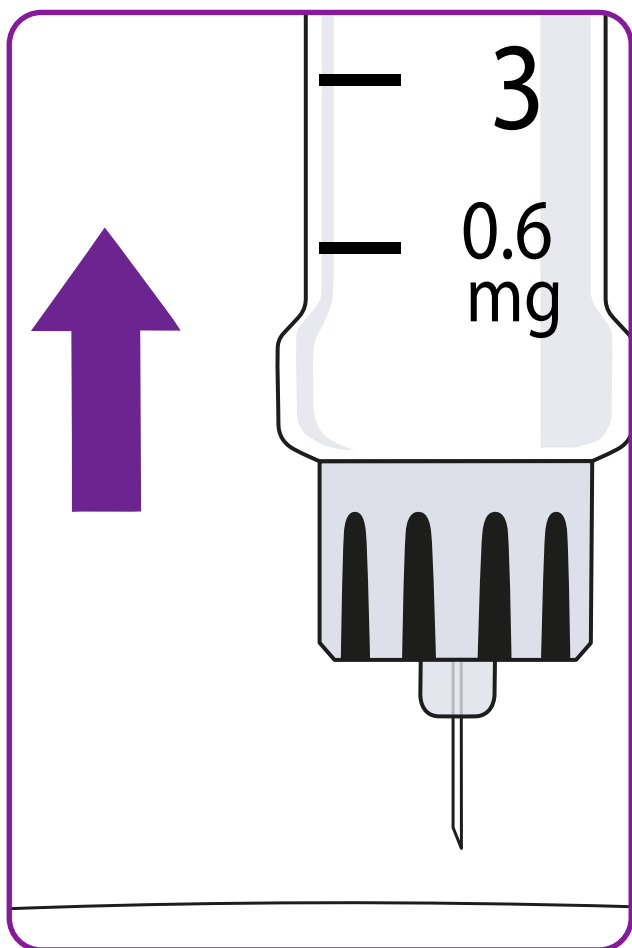
Keep the needle in your skin after the dose counter has returned to 0 and count slowly to 6. If the needle is removed earlier, you may see a stream of solution coming from the needle tip, meaning the full dose has not been delivered.



Remove the needle from the skin and release the dose button.

If blood appears at the injection site, you should press lightly, but do not rub the area. You may see a drop of solution at the needle tip after injecting. This is normal and does not affect the dose.

Always watch the dose counter to know how many mg you are injecting. Hold the dose button down until the dose counter shows 0.



How to identify a blocked or damaged needle?

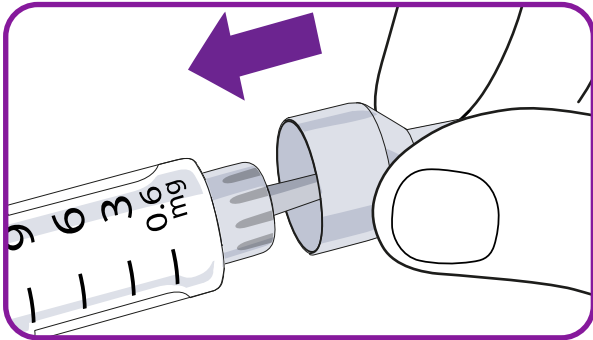
- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- In this case, you will have not received any medicine, even though the dose counter has moved from the original dose that you have set.

How to handle a blocked needle?

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

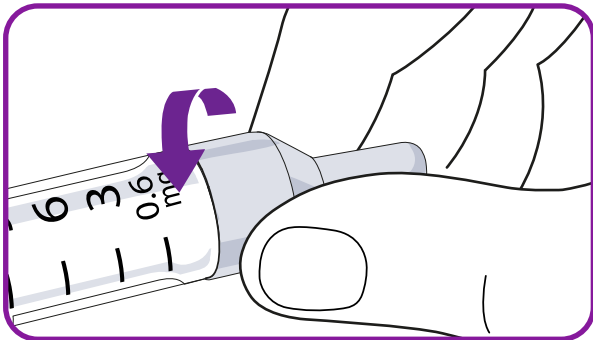


After your Nevolat[®] Injection



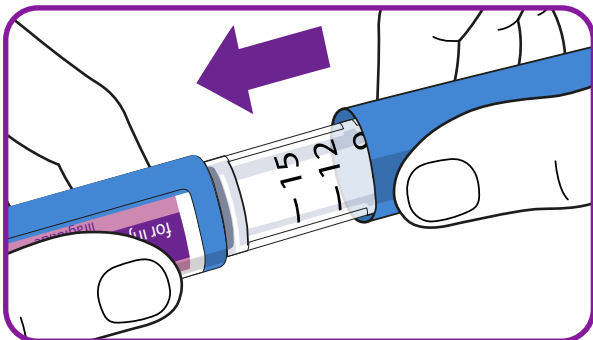
Guide the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap.

Once the needle is covered, carefully push the outer needle cap completely on.



Unscrew the needle and dispose of it carefully.

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



Always dispose the needle after each injection.

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

Do not try to put the inner needle cap back on the needle. You may risk sticking yourself with the needle.

Always remove the needle from the pen after each injection. This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.

Managing Common Side Effects of Nevolat®

Taking Nevolat® can sometimes cause side effects. Here are some common ones and tips on how to manage them:



Nausea

What to do: Try taking Nevolat with food. Eating small, frequent meals can also help. Ginger tea or ginger candies might soothe your stomach.

When to call your doctor: If nausea is severe or doesn't go away, contact your healthcare provider.



Vomiting

What to do: Stay hydrated by drinking small sips of water frequently. Avoid large meals and stick to bland foods.

When to call your doctor: If vomiting is persistent or severe, seek medical advice.



Diarrhoea

What to do: Drink plenty of fluids to stay hydrated. Avoid fatty or spicy foods that might worsen diarrhoea.

When to call your doctor: If diarrhoea is severe or doesn't improve, contact your healthcare provider.



Constipation

What to do: Increase your intake of dietary fiber by eating fruits, vegetables, and whole grains. Drink plenty of water and stay active.

When to call your doctor: If constipation is severe or persistent, consult your healthcare provider.



Dizziness

What to do: Stand up slowly from sitting or lying positions. Avoid driving or operating heavy machinery if you feel dizzy.

When to call your doctor: If dizziness is severe or doesn't improve, consult your healthcare provider.



Headache

What to do: Drink plenty of water and rest in a quiet, dark room. Over-the-counter pain relievers may help, but check with your doctor first.

When to call your doctor: If headaches are severe or frequent, seek medical advice.



Dry Mouth

What to do: Sip water regularly, chew sugar-free gum or suck on sugar-free candies. Avoid caffeine and alcohol, as they can make dry mouth worse.

When to call your doctor: If dry mouth is bothersome or persistent, talk to your doctor.



Low Blood Sugar (hypoglycaemia)

What to do: Eat or drink something sugary, like fruit juice or a sugary snack. Follow up with a carbohydrate, such as a sandwich or a piece of fruit.

When to call your doctor: If you experience frequent episodes of low blood sugar or if symptoms are severe.

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

Serious side effects

While taking Nevolat, some serious side effects may occur. These can include severe allergic reactions, pancreatitis, and kidney problems. Symptoms of a severe allergic reaction can include difficulty breathing, swelling of the face, lips, tongue, or throat, and a severe rash. If you experience any of these symptoms, seek medical attention immediately.

Pancreatitis is another serious side effect that can occur. Symptoms include severe abdominal pain that may spread to your back, nausea, and vomiting. If you notice these symptoms, it is crucial to contact your healthcare provider right away.

Kidney problems can also arise while taking Nevolat. Signs of kidney issues include changes in the amount of urine, swelling in your legs or ankles, and feeling very tired. If you experience any of these symptoms,

inform your doctor as soon as possible.

Always follow your doctor's instructions and report any side effects you experience. Your healthcare team is there to help you manage any issues and ensure your treatment is as comfortable as possible.

Reporting side effects

If you experience any side effects, whether common or serious, it's important to report them. You can report side effects to your healthcare provider, who can provide advice and support. Additionally, you can report side effects directly to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card Scheme. This helps ensure the safety of medicines and allows for the monitoring of any new side effects.

To report side effects through the Yellow Card Scheme, you can:

- Visit the Yellow Card website
- Download the Yellow Card app on your smartphone
- Call the Yellow Card hotline at 0800 731 6789

You can also report side effects to Zentiva directly via:

- Email: UKmedinfo@zentiva.com
 - Phone: 0800 090 2408
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How to store Nevolat[®]?

Keep Nevolat[®] out of the sight and reach of children.

Do not use Nevolat[®] after the expiry date which can be found 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 (2–8°C). Keep away from the freezer compartment. Do not freeze.



After Use

After first use, you can keep and use the pen for 30 days, as long as it is stored at a temperature below 30°C or in a refrigerator (2–8°C), away from the freezer compartment. Do not freeze.

When you are not using the pen, keep the pen cap on to protect the medication from the light.

Do not use this medicine if the solution is not clear and colourless 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.

The Importance of Healthy Lifestyle Choices

Managing weight effectively is a multifaceted journey that involves more than just medication. For people on daily liraglutide medication, integrating healthy lifestyle choices can significantly enhance the benefits of the treatment and lead to sustainable weight management.

Here's why adopting a healthy lifestyle is crucial

1. Enhanced Medication Efficacy

Nevolat® helps regulate appetite and blood sugar levels, aiding weight loss. Its effectiveness improves with regular physical activity and a balanced diet, leading to better outcomes.

2. Improved Overall Health

Healthy lifestyle choices, like a nutritious diet and regular exercise, enhance overall well-being and reduce the risk of chronic diseases such as diabetes and hypertension.

3. Sustainable Weight Loss

Nevolat® can initiate weight loss, but maintaining it requires long-term lifestyle changes. Healthy eating and regular exercise are key to preventing weight regain after stopping medication.

4. Mental and Emotional Well-being

Regular exercise releases endorphins, improving mood and reducing stress. A balanced diet positively affects mood and energy levels, helping you stay motivated and committed to your goals.



Healthy lifestyle tips

Healthy eating and regular exercise can help you manage your blood sugar levels. They can also help you reduce the risk of complications. Here are some handy tips to help you make healthier food choices and move more.



Choose healthier carbohydrates, such as whole grains (brown rice, whole oats), fruit, vegetables, pulses (chickpeas, beans) and dairy (unsweetened yoghurt and milk).



Eat less salt. Try to limit yourself to a maximum of 6g (one teaspoonful) of salt per day.



Swap red and processed meat for pulses, eggs, fish, poultry (chicken, turkey) and unsalted nuts.



Start exercising slowly with 'warmups' and increase your activity levels gradually to prevent injuries. Begin with small changes, such as moving more around the house; activities like hoovering, washing your car, or watering plants can all make a difference.



Keep active whilst you're on the move. For example, you can get off the bus or tube one stop earlier, park further away from your destination, take the stairs, and walk or cycle wherever possible.

Use the space below to jot down your exercise goals while undergoing treatment. This can help you stay focused and motivated.

FAQs

Will I need regular check-ups with the doctor whilst administering Nevolat®?

Yes, you should schedule a check-up after 3 months with your doctor to ensure you are taking the medicine correctly, it is helping you to lose weight and any minor side effects are under control.

How long will I stay on Nevolat®?

Addressing and managing obesity usually requires long-term treatment, but you can support this treatment by following a healthy diet and exercising regularly. Always stay on treatment until your doctor tells you to stop.

Will my doctor or nurse show me how to administer my injections?

Nevolat® is a self-injectable medicine that is supplied in a pre-filled pen. Once prescribed, your healthcare provider will demonstrate how to inject it. After this, you can follow the guidance in this booklet or on our website (www.liraglutide.co.uk)

Use the patient information leaflet to remind you of the steps. If you have questions or do not understand the instructions, ask your healthcare providers or pharmacists for guidance.



When should I take Nevolat®?

Nevolat® can be taken at any time, independent of meals. However, it is easiest to take it at the same time every day, to make sure it's convenient and simple to remember.



Can Nevolat® interact with other medications?

As with most medicines, there can be some interactions with other medications. It is worth bearing in mind that the slowing down how food is emptied from the stomach seen with liraglutide and any side effects of diarrhoea or vomiting may affect the absorption of oral medicinal products you are taking.

Nevolat® did not change the overall exposure of paracetamol, atorvastatin, griseofulvin and insulin detemir, so no dose adjustment is required. Although there are pharmacokinetic changes following co-administration, these are not considered to be clinically relevant and no dose adjustment is required for those taking liraglutide and digoxin, lisinopril and oral contraceptives.



Does Nevolat® need to be refrigerated when travelling?

Ideally yes, but there are sometimes unavoidable occasions, during travel, when Nevolat® will be out of a temperature-controlled environment. Although evidence has shown that Nevolat® should still be effective for several days at room temperature, refrigerating (between 2-8 degrees C) it whenever possible ensures it is effective. When travelling by plane, car or train, store your medication in an insulated bag with cold packs to help keep it stored within the correct temperature range. Position the cold packs carefully so they don't directly touch the pen. Remember to also keep the pen out of direct sunlight.



Can I drink alcohol while using Nevolat®?

Although there are no known interactions between Nevolat® and alcohol, alcohol consumption can affect blood sugar levels. Consuming alcohol during treatment could possibly worsen some of the drug's side effects, for example, worsened headache or diarrhoea. If you have questions about drinking alcohol whilst taking Nevolat®, please discuss with your doctor.



Notes

Please use this space to add any notes from your doctor



Notes

Please use this space to add any notes from your doctor



For further information on Nevolat® (liraglutide) and weight management please visit www.liraglutide.co.uk