

# ARX-Liraglutide

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using ARX-Liraglutide?

ARX-Liraglutide contains the active ingredient liraglutide. ARX-Liraglutide is used in weight loss, in addition to diet and exercise in adults aged 18 years or older.

For more information, see Section [1. Why am I using ARX-Liraglutide?](#) in the full CMI.

### 2. What should I know before I use ARX-Liraglutide?

Do not use if you have ever had an allergic reaction to liraglutide or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ARX-Liraglutide?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with liraglutide and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ARX-Liraglutide?

- Your doctor or pharmacist will have given you advice on how to use your medicine.
- The usual starting dose of ARX-Liraglutide is 0.6 mg once per day, which will be increased step wise until reaching the recommended dose of 3.0 mg once a day.

More instructions can be found in Section [4. How do I use ARX-Liraglutide?](#) in the full CMI.

### 5. What should I know while using ARX-Liraglutide?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist or health professional you visit that you are using ARX-Liraglutide.</li><li>• Tell your doctor if you have diabetes, or a racing heartbeat when at rest.</li><li>• Do not use ARX-Liraglutide in combination with other medicines that contain GLP-1 receptor agonists.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how ARX-Liraglutide affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• n/a</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Before opening, store ARX-Liraglutide pens in a refrigerator (2°C to 8°C). Do not freeze.</li><li>• During use, ARX-Liraglutide pens can be stored for 30 days either at room temperature (below 30°C) or in a refrigerator (2°C to 8°C). Store the pen without a needle attached.</li></ul>

For more information, see Section [5. What should I know while using ARX-Liraglutide?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects are feeling sick (nausea), being sick (vomiting), diarrhoea, constipation, headache, changed sense of taste, dizziness, indigestion (dyspepsia), feeling bloated, burping, wind (flatulence) or dry mouth, heartburn, painful or swollen abdomen, low blood sugar (a hypo), injection site reactions, fast heartbeat, feeling weak or tired, difficulty sleeping (insomnia), increase of pancreatic enzymes and rash. More serious side effects include severe and persistent pain in the abdomen, lump or swelling in the neck, hoarseness, trouble swallowing or shortness of breath, signs of reduced kidney function, signs of gallbladder problems and depression.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# ARX-Liraglutide

Active ingredient(s): *Liraglutide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-Liraglutide. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARX-Liraglutide.**

Where to find information in this leaflet:

- [1. Why am I using ARX-Liraglutide?](#)
- [2. What should I know before I use ARX-Liraglutide?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARX-Liraglutide?](#)
- [5. What should I know while using ARX-Liraglutide?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ARX-Liraglutide?

ARX-Liraglutide contain the active ingredient **liraglutide**, similar to a naturally occurring hormone called **GLP-1** that is released from the intestine after a meal.

ARX-Liraglutide is used for weight loss, in addition to diet and exercise, in adults aged 18 years and above who have:

- a BMI of 30 or more (obese), or
- a BMI of 27 or more and less than 30 (overweight) and weight related health problems (such as diabetes, high blood pressure, abnormal levels of fats in the blood or breathing problems during sleep, called 'obstructive sleep apnoea').

ARX-Liraglutide should be used with a reduced calorie diet and increased physical activity.

BMI (Body Mass Index) is a simple measure of your weight in relation to your height. It is calculated by dividing your weight in kg by your height in metres squared.

ARX-Liraglutide works by acting on receptors in the brain that control your appetite, causing you to feel fuller and less hungry. This may help you eat less food and reduce your body weight.

Weight loss normally starts within 2 weeks and continues for 9 to 12 months on ARX-Liraglutide treatment. ARX-Liraglutide may then help you to maintain this new lower weight and help to prevent weight being regained.

ARX-Liraglutide is not addictive.

## 2. What should I know before I use ARX-Liraglutide?

### Warnings

**Do not use ARX-Liraglutide if:**

- You are allergic to liraglutide, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.
- Always check the ingredients to make sure you can use this medicine
- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes
- It is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering
- It has expired or is damaged, return it to your pharmacist for disposal. The expiry date refers to the last day of that month.

**Check with your doctor if:**

- you have palpitations (you feel aware of your heartbeat) or if you have feelings of a racing heartbeat while at rest during ARX-Liraglutide treatment.
- you have diabetes. Do not use ARX-Liraglutide as a replacement for insulin. ARX-Liraglutide and insulin should not be used together.
- you have heart failure (disease of the heart with shortness of breath, and swelling of the feet or legs due to fluid build-up). The use of ARX-Liraglutide is not recommended if you have severe heart failure.
- you are taking any other weight loss medications, including prescription, over the counter or herbal medicines.
- you have inflammatory bowel disease, such as Crohn's disease.
- you have gastroparesis (a condition in which your stomach has difficulty in emptying food properly).
- you currently have or have had thyroid disease, including thyroid nodules and enlargement of the thyroid gland.

- you have kidney disease or are on dialysis (a treatment where your blood is filtered and purified using a machine).
- you have liver problems
- you have or have had a disease of the pancreas.
- you have or have had depression, suicidal thoughts or any other major mental illness.
- you have other medical conditions or have taken other medicines that may have caused you to gain weight.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Use of this medicine in pregnancy has not been studied. ARX-Liraglutide should not be used during pregnancy. It is not known if ARX-Liraglutide may harm your unborn child.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if liraglutide passes into breast milk. Do not use ARX-Liraglutide if you are breast-feeding.

### Effects on the digestive system

- **Drink plenty of fluids to avoid dehydration, particularly if you experience vomiting or diarrhoea when beginning treatment with ARX-Liraglutide.**  
Dehydration can cause kidney problems that sometimes require dialysis.

### Inflammation of the pancreas

**Stop taking ARX-Liraglutide and contact a doctor immediately if you experience severe pain in your upper abdomen, usually worse on the right side under the ribs.**

The pain may be felt through to your back or right shoulder. If you lose substantial weight, you are at risk of gallstones and thereby inflamed gallbladder.

### Children and adolescents

ARX-Liraglutide should not be used in children and adolescents under 18 years. This is because the effects of this medicine have not been studied in this age group.

### Use in the elderly

There is little experience with liraglutide in patients  $\geq$  75 years old. It is not recommended if you are 75 years or older.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with ARX-Liraglutide and affect how it works.**

**In particular, tell your doctor or pharmacist if you are using the following medicines:**

- for the treatment of type 2 diabetes, such as a sulfonylurea (including glimepiride or glibenclamide). You may get low blood sugar (hypoglycaemia) when you use these medicines with ARX-Liraglutide. Your doctor may adjust the dose of your diabetes medicine to prevent you from getting low blood sugar.
- to thin your blood (anticoagulants), such as warfarin or other types of medicines called 'coumarin derivatives'. Your doctor may need to monitor you more closely.
- for high blood pressure, such as amlodipine, atenolol or bisoprolol or for heart disease, such as digoxin.
- for HIV, such as atazanavir or ritonavir.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARX-Liraglutide.**

## 4. How do I use ARX-Liraglutide?

Your doctor or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions. They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor, nurse or pharmacist for help.**

Your doctor will start you on a diet and exercise programme. Stay on this programme while you are using ARX-Liraglutide.

### How much to use

Your doctor will tell you how much of this medicine you need to use each day.

- The usual starting dose is 0.6 mg once a day.
- Your doctor will tell you how long to keep taking this dose. It will be for at least one week.
- Your dose may then be increased by 0.6 mg each week until you reach the recommended dose of 3.0 mg once a day.
- Your doctor will tell you how much ARX-Liraglutide to use each week. Usually, you will be told to follow the table below:

Week	Dose to inject
Week 1	0.6 mg once a day
Week 2	1.2 mg once a day
Week 3	1.8 mg once a day
Week 4	2.4 mg once a day
Week 5 onwards	3.0 mg once a day

Once you reach the recommended dose of 3.0 mg in Week 5 of treatment, keep using this dose until your treatment period ends. Do not increase your dose further.

Visit your doctor on a regular basis to assess your need for continued treatment with ARX-Liraglutide.

Do not change your dose unless your doctor has told you to.

Follow the instructions provided and use ARX-Liraglutide until your doctor tells you to stop.

### When to use ARX-Liraglutide

You can use ARX-Liraglutide at any time of day, with or without food and drinks. It is preferable to use ARX-Liraglutide at about the same time each day, at a time that is most convenient for you.

Only continue using ARX-Liraglutide if you have lost at least 5% of your initial body weight after 12 weeks on the 3.0 mg/day dose. Consult your doctor before you continue.

### How to use ARX-Liraglutide

Before you use the pen for the first time, your doctor or nurse will show you how to use the pen.

- ARX-Liraglutide pre-filled pen is designed to be used with 32G needles, up to a length of 8 mm. Needles are not included with the pen.
- Ask your doctor or nurse which needle width (gauge) and length is best for you.
- Use a new needle for each injection and dispose of it after use.
- ARX-Liraglutide is given as an injection under the skin (subcutaneous injection) as shown to you by your doctor or nurse. **Never inject ARX-Liraglutide into a vein or muscle.**
- ARX-Liraglutide may be injected into the front of your waist (abdomen), the front of your thigh, or your upper arm.
- Change the place within the area where you inject each day to reduce the risk of developing lumps under the skin. See Section 6. [Are there any side effects?](#)

#### Checking your ARX-Liraglutide pen:

ARX-Liraglutide should be clear and colourless.

**Do not use this medicine if it is thickened, coloured, or has solid bits in it.**

Read Section 8. [Instructions for use](#) carefully in order to prepare and handle your ARX-Liraglutide pen correctly.

### If you forget to use ARX-Liraglutide

If you forget a dose and remember it within 12 hours from when you usually take the dose, inject ARX-Liraglutide as soon as you remember.

However, if more than 12 hours have passed since you should have used ARX-Liraglutide, skip the missed dose and inject your next dose the following day at the usual time.

**Do not use an extra dose or increase the dose on the following day to make up for the missed dose.**

**If you are not sure what to do, talk to your doctor, nurse or pharmacist.**

### If you use too much ARX-Liraglutide (overdose)

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Accident and Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Take the medicine pack with you. You may need medical treatment. Using too much liraglutide may cause nausea (feeling sick), vomiting (being sick), or low blood sugar (hypoglycaemia), see Section 6. [Are there any side effects?](#) for the early warning signs of hypos.

## 5. What should I know while using ARX-Liraglutide?

### Things you should do

**Tell your doctor if you have diabetes.**

They may adjust the dose of your diabetes medicine to prevent you getting 'hypos' (low blood sugar levels).

- Do not mix ARX-Liraglutide with other medicines that you inject (e.g. insulins).
- Do not use ARX-Liraglutide in combination with other medicines that contain GLP-1 receptor agonists (e.g. exenatide, dulaglutide, semaglutide or lixisenatide).

**Tell your doctor, nurse or pharmacist if you are travelling.**

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may not be able to get ARX-Liraglutide in the country you are visiting.

Your doctor, nurse or pharmacist can provide you with some helpful information.

Remind any doctor, dentist or pharmacist or other health professional you visit that you are using ARX-Liraglutide.

### Things you should not do

**Do not stop using your medicine unless your doctor tells you to.**

**Do not use the medicine if you think it has been frozen or exposed to excessive heat.**

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

**Do not share needles or pens.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how the ARX-Liraglutide affects you.**

For further information talk to your doctor or pharmacist.

### Looking after your medicine

- Store ARX-Liraglutide pens *that are not being used* between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element). Do not freeze.
- When ARX-Liraglutide is being used, you can keep the pen for 30 days either at room temperature (below 30°C) or in a refrigerator (2°C to 8°C), away from the cooling element. Store the pen without a needle attached.
- The medicine in ARX-Liraglutide must not be frozen, or exposed to heat or direct sunlight.
- When you are not using the pen, keep the pen cap on in order to protect it from light.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

### When to discard your medicine

**Discard ARX-Liraglutide after 30 days even if there is still some medicine left in it.**

**Do not use ARX-Liraglutide after the expiry date printed on the pen label and carton. The expiry date refers to the last day of that month.**

**Do not use ARX-Liraglutide if the solution is not clear and colourless.**

### Getting rid of any unwanted medicine

**Dispose of used needles safely into a yellow plastic sharps container.**

**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Very common:</b> may affect more than 1 in 10 people:</p> <ul style="list-style-type: none"> <li>• feeling sick (nausea)</li> <li>• being sick (vomiting)</li> <li>• diarrhoea</li> <li>• constipation</li> <li>• headache</li> </ul> <p>these usually go away after a few days or weeks.</p> <p><b>Common:</b> may affect up to 1 in 10 people:</p> <ul style="list-style-type: none"> <li>• changed sense of taste</li> <li>• dizziness</li> <li>• indigestion (dyspepsia)</li> <li>• inflammation in the lining of the stomach (gastritis)</li> <li>• feeling bloated, burping, wind (flatulence), or dry mouth</li> <li>• heartburn</li> <li>• stomach discomfort</li> <li>• upper stomach pain</li> <li>• gall stones</li> <li>• low blood sugar (a 'hypo')</li> <li>• injection site reactions (such as bruising, pain, irritation, itching and rash)</li> <li>• feeling weak or tired</li> <li>• difficulty sleeping (insomnia) This usually occurs during the first 3 months of treatment</li> <li>• increase of pancreatic enzymes (such as lipase and amylase).</li> </ul> <p><b>Uncommon:</b> may affect up to 1 in 100 people:</p> <ul style="list-style-type: none"> <li>• fast heartbeat</li> <li>• feeling generally unwell</li> <li>• inflamed gall bladder</li> <li>• allergic reactions including skin rash</li> <li>• delay in the emptying of the stomach</li> <li>• loss of fluids (dehydration)</li> </ul> <p>This is more likely to occur at the start of treatment and may be due to you being sick (vomiting), feeling sick (nausea), and diarrhoea.</p> <p><b>Not known:</b> frequency cannot be estimated from the available data</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>Lumps under the skin may be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known).</li> </ul> <p>ARX-Liraglutide may not work very well if you inject into a lumpy area.</p> <p>Change the injection site with each injection to help prevent this skin change.</p>	
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## Hypoglycaemia

Hypos are more likely to occur if you have diabetes and are also taking a sulfonylurea. A hypo may come on suddenly. The warning signs of a hypo can include:

- cold sweat, cool pale skin
- headache
- fast heartbeat
- feeling sick
- feeling very hungry
- changes in vision
- feeling sleepy
- feeling weak, nervous, anxious, or confused
- difficulty concentrating
- shaking (tremor)

Your doctor can provide you with further information about how to treat low blood sugar levels and what to do if you notice these warning signs. If you are already taking a sulfonylurea when you start using ARX-Liraglutide your doctor may tell you to reduce the dose of the sulfonylurea.

## Serious side effects

Serious side effects	What to do
<p><b>Inflamed pancreas (pancreatitis)</b></p> <ul style="list-style-type: none"> <li>severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting. Pancreatitis is a serious, potentially life-threatening medical condition. <b>Stop taking ARX-Liraglutide if you experience this.</b></li> </ul> <p><b>Reduced kidney function</b></p> <ul style="list-style-type: none"> <li>signs may include reduction in urine volume, a metallic taste in your mouth and bruising easily.</li> </ul> <p><b>Gallbladder problems</b></p>	<p><b>Call your doctor straight away, or go straight to the Accident and Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<ul style="list-style-type: none"> <li>signs may include upper right side abdominal pain, yellowing of the skin and eyes or clay coloured stools</li> </ul> <p><b>Severe allergic reactions</b> (anaphylaxis). Symptoms include:</p> <ul style="list-style-type: none"> <li>skin rashes over a large part of the body</li> <li>shortness of breath, wheezing</li> <li>swelling of the face, lips or tongue</li> <li>fast pulse</li> <li>sweating</li> </ul> <p><b>Mood changes</b></p> <ul style="list-style-type: none"> <li>depression or any mental changes (especially sudden changes in mood, behaviours, thoughts or feelings) that are new, worse or worry you.</li> </ul> <p><b>Goitre</b></p> <ul style="list-style-type: none"> <li>a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath.</li> </ul> <p>These side effects are rare.</p> <p><b>Bowel obstruction*</b></p> <ul style="list-style-type: none"> <li>A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.</li> </ul> <p>*frequency not known</p>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ARX-Liraglutide contains

Active ingredient (main ingredient)	liraglutide 6 mg/mL
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<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• phenol</li><li>• dibasic sodium phosphate dihydrate</li><li>• Propylene glycol</li><li>• sodium hydroxide</li><li>• hydrochloric acid</li><li>• water for injections.</li></ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

### **What ARX-Liraglutide looks like**

ARX-Liraglutide is supplied as a sterile, aqueous, clear and colourless or almost colourless solution for injection in a pre-filled pen. Each pen contains 3 mL of solution, and is able to deliver doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg.

ARX-Liraglutide is available in packs containing 1, 3 or 5 pens. Not all pack sizes may be marketed. Needles are not included.

**AUST R 424370**

### **Who distributes ARX-Liraglutide**

Arrotex Pharmaceuticals Pty Ltd.,  
15-17 Chapel St,  
Cremorne VIC 3121.  
[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in August 2024.

## 8. INSTRUCTIONS FOR USE

### Instructions on how to use ARX-Liraglutide 6 mg/mL solution for injection in pre-filled pen

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

**Do not use the pen without proper training** from your doctor or nurse.

Start by checking your pen to **make sure that it contains ARX-Liraglutide 6 mg/mL**, 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 is trained to use the ARX-Liraglutide pre-filled pen.

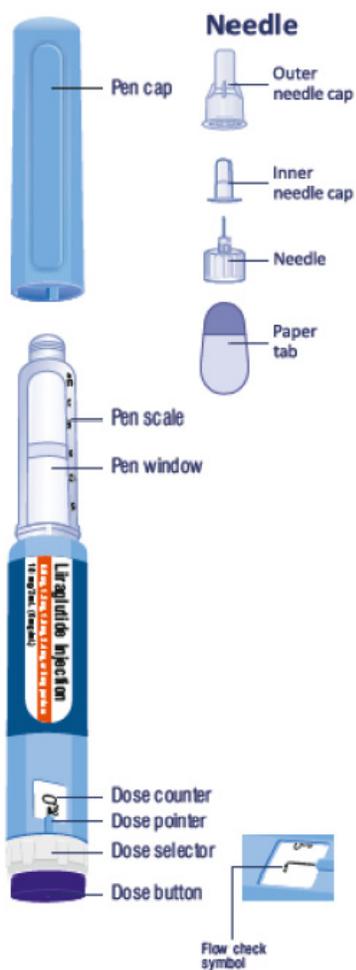
Your pen is a pre-filled dial-a-dose pen. It contains 18 mg of liraglutide, and delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg and 3.0 mg. Your pen is designed to be used with 32G disposable needles up to a length of 8 mm.

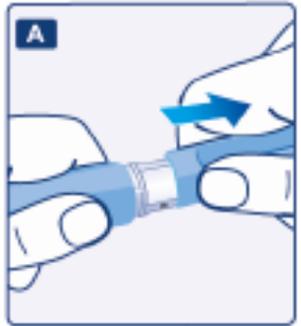
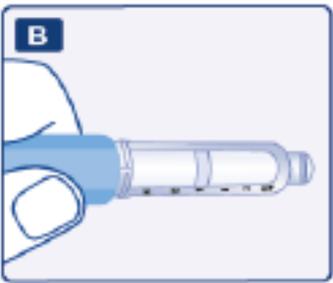
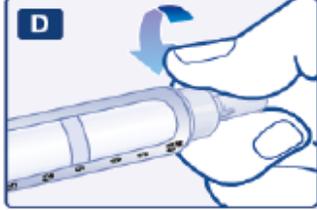
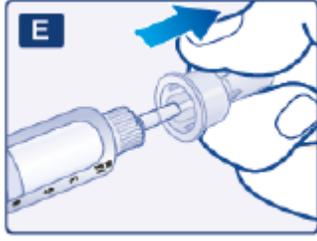
Needles are not included in the pack.

#### Important information

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

#### ARX-Liraglutide pre-filled pen and needle (example)



<p><b>1 Prepare your pen with a new needle</b></p> <ul style="list-style-type: none"> <li>• <b>Check the name and coloured label</b> of your pen, to make sure that it contains ARX-Liraglutide. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.</li> <li>• <b>Pull off the pen cap.</b></li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Check that the solution in your pen is clear</b> and colourless. Look through the pen window. If the solution looks cloudy, do not use the pen.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Take a new 32G needle</b> and tear off the paper tab.</li> </ul>	<p style="text-align: center;"><b>Needle</b></p> 
<p><b>Make sure to attach the needle correctly.</b></p> <ul style="list-style-type: none"> <li>• Push the needle <b>straight</b> onto the pen.</li> <li>• Turn until it is on <b>tight</b>.</li> </ul>	
<p><b>The needle is covered by two caps. You must remove both caps.</b> If you forget to remove both caps, you will <b>not</b> inject any solution.</p> <ul style="list-style-type: none"> <li>• <b>Pull off the outer needle cap and keep it for later.</b> You will need it after the injection, to safely remove the needle from the pen.</li> </ul>	

**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.

**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.**

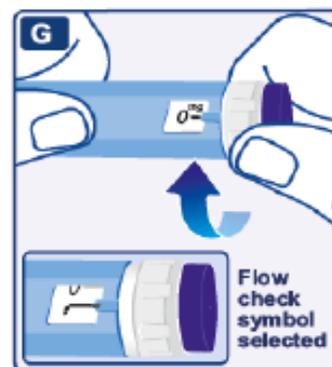
This may prevent blocked needles, contamination, infection and inaccurate dosing.

⚠ **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 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.

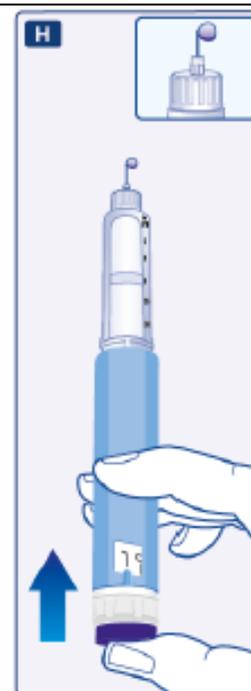
**If no drop appears**, repeat step 2 'Check the flow with each new pen' up to 6 times. If there is still no drop, change the needle and repeat step 2 'Check the flow with each new pen' once more.

**If a drop still does not appear**, dispose of the pen and use a new one.

⚠ **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 ARX-Liraglutide.



### 3 Select your dose

- Turn the dose selector until the dose counter shows your dose (0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg).

If you select the wrong dose, you can turn the dose selector forward or backwards to the correct dose.

The pen can dial up to a maximum of 3.0 mg.

The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select per dose.

You can select up to 3.0 mg per dose. When your pen contains less than 3.0 mg the dose counter stops before 3.0 is shown.

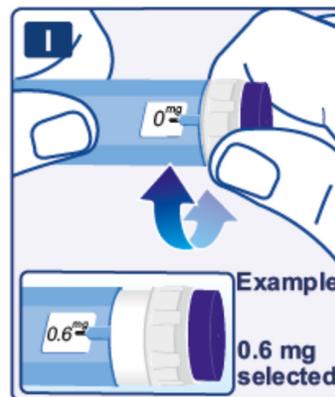
The dose selector clicks differently when turned forward, backwards or past the number of mg left. Do not count the pen clicks.

- ⚠ Always use the dose counter and the dose pointer to see how many mg you have selected before injecting this medicine.

Do not count the pen clicks.

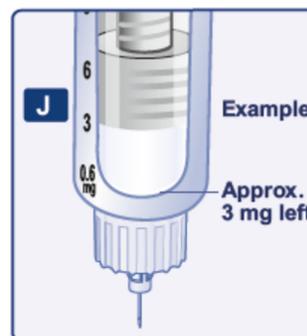
Do not use the pen scale. It only shows approximately how much solution is left in your pen.

**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 that you get a correct dose.



### How much solution is left?

- The pen scale shows you approximately how much solution is left in your pen.



- To see precisely how much solution is left, use the dose counter:

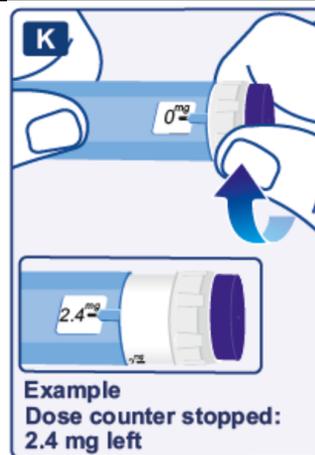
Turn the dose selector until the dose counter stops.

If it shows 3.0, at least 3.0 mg are left in your pen. If the dose counter stops before 3.0 mg, there is not enough solution left for a full dose of 3.0 mg.

### If you need more medicine than what is left in your pen

Only if trained or advised by your doctor or nurse, you may split your dose between your current pen and a new pen. Use a calculator to plan the doses as instructed by your doctor or nurse.

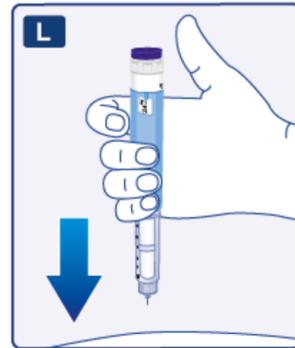
- ⚠ Be very careful to calculate correctly.



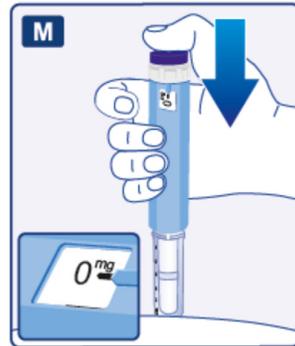
If you are not sure how to split your dose using two pens, then select and inject the dose you need with a new pen.

#### 4 Inject your dose

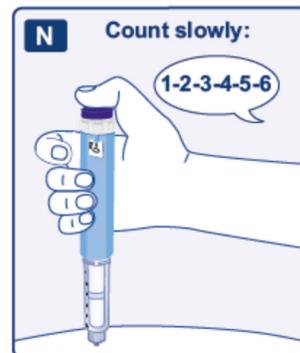
- **Insert the needle into your skin** as your doctor or nurse has shown you.
- **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.



- **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.



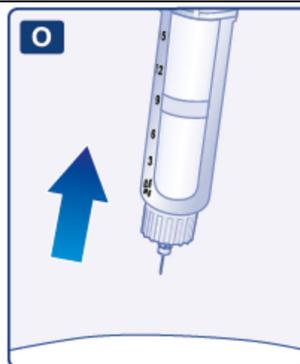
- **Remove the needle from your skin.** You can then release the dose button.

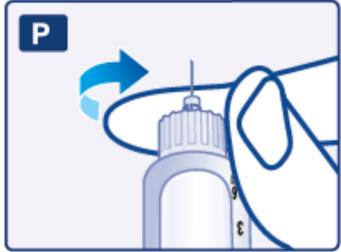
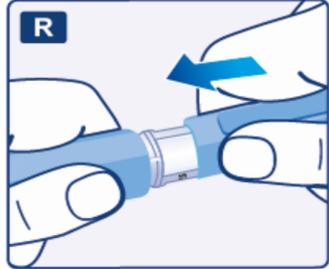
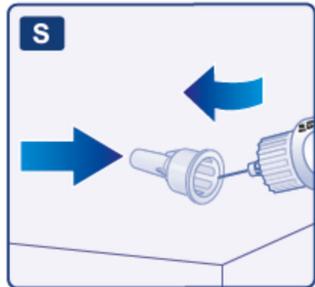
If blood appears at the injection site, press lightly.

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 shows 0.

**How to identify a blocked or damaged needle?**



<ul style="list-style-type: none"> <li>• If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.</li> <li>• In this case - you have <b>not</b> received <b>any</b> medicine - even though the dose counter has moved from the original dose that you have set.</li> </ul> <p><b>How to handle a blocked needle?</b></p> <p>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.</p> <p><b>Never touch the dose counter when you inject.</b> This can interrupt the injection.</p>	
<p><b>5 After your injection</b></p> <ul style="list-style-type: none"> <li>• <b>Always dispose of the needle after each injection</b> to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will not inject any medicine.</li> <li>• <b>Carefully remove the needle from the pen.</b> Do not put the needle caps back on the needle, to avoid needle sticks.</li> </ul>	<p style="text-align: center;"><b>Needle</b></p> 
<ul style="list-style-type: none"> <li>• <b>Place the needle in a sharps container</b> right away to reduce the risk of needle sticks.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Put the pen cap on your pen</b> after each use to protect the solution from light.</li> </ul> <p>⦿ If you do not have a sharps container, follow a 1-handed needle recapping method. Carefully slip the needle into the outer needle cap. Dispose of the needle in a sharps container as soon as possible.</p> <p>When the pen is empty, throw it away <b>without</b> a needle on as instructed by your doctor, nurse, pharmacist or local authorities.</p> <p>⚠ <b>Never try to put the inner needle cap back on the needle.</b> You may stick yourself with the needle.</p> <p>⚠ <b>Always remove the needle from your pen after each injection.</b></p>	 

<p>This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.</p>	
<p> Further important information</p> <ul style="list-style-type: none"> <li>• Always keep your pen and needles <b>out of sight and reach of others, especially children.</b></li> <li>• <b>Never share</b> your pen or your needles with other people.</li> </ul> <p>Caregivers must <b>be very careful when handling used needles</b> – to prevent needle injury and cross-infection.</p>	
<p><b>Caring for your pen</b></p> <ul style="list-style-type: none"> <li>• <b>Do not leave the pen in a car</b> or other place where it can get too hot or too cold.</li> <li>• <b>Do not inject ARX-Liraglutide which has been frozen.</b> If you do that, you may not get the intended effect of this medicine.</li> <li>• <b>Do not expose your pen to dust, dirt or liquid.</b></li> <li>• <b>Do not wash, soak or lubricate your pen.</b> It may be cleaned with a mild detergent on a moistened cloth.</li> <li>• <b>Do not drop your pen</b> 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.</li> <li>• <b>Do not try to refill your pen.</b> Once empty, it must be disposed of.</li> <li>• <b>Do not try to repair your pen</b> or pull it apart.</li> </ul>	