AWIQLI® FLEXTOUCH® SOLUTION FOR INJECTION IN PRE-FILLED PEN

Insulin Icodec 700 units/mL

What is in this leaflet

What Awiqli® is used for

Awiqli® is used to treat diabetes in adults. It is a type of insulin called a 'long-acting basal insulin'.

Diabetes is a disease where your body does not produce enough insulin (a hormone that controls the amount of blood sugar in the body).

How Awiqli® works

Awiqli® contains the active substance insulin icodec, is a replacement insulin that acts in the same way as naturally produced insulin but works for a longer time. This means that it produces a long and steady blood sugar lowering action. It therefore only needs to be injected once a week.

Before you use Awiqli®

- ***When you must not use it***

Do not use Awiqli®

- if you are allergic to insulin icodec or any of the other ingredients of this medicine (listed in Product Description).

- ***Before you start to use it***

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Awiqli® (listed in Product Description).

Before you use Awiqli® it is important that you are aware of the following:

- Hypoglycaemia (low blood glucose levels) can occur if your dose of Awiqli® is too high or if you miss a meal or undertake unplanned, strenuous physical exercise. Other factors that can increase the risk of hypoglycaemia include change of the injection area, illness (such as vomiting, diarrhoea and fever), alcohol consumption and use of other medicines. Symptoms of hypoglycaemia usually occur suddenly (see information in the box at the end of this leaflet). Severe hypoglycaemia may lead to loss of consciousness and/or seizures and may result in temporary or permanent impairment of brain function or even death. If you experience hypoglycaemia, follow the guidance in the box at the end of this leaflet for low blood sugar.
- If you have type 1 diabetes, the occurrence of hypoglycaemia could be higher.
- Hyperglycaemia (high blood glucose levels) can occur if the dose of Awiqli® is insufficient and/or if treatment is discontinued or if you have an associated illness, particularly an infection. Symptoms of hyperglycaemia usually develop gradually over a period of hours or days (see information in the box at the end of this leaflet). Untreated hyperglycaemia may lead to diabetic ketoacidosis (a serious complication of diabetes with high levels of ketones in the blood). If you experience hyperglycaemia, follow the guidance in the box at the end of this leaflet for high blood sugar level.
- Switching from other insulin medicines – your doctor may need to adjust the insulin dose if you switch from once or twice a day basal insulin to once a week Awiqli®. It is important that you always check that you inject the correct dose, particularly for the first and second injections of Awiqli® since your doctor may prescribe you an increased dose for the first injection followed by a lower dose. Always follow your doctor's recommendation on how much medicine you should take. Please see How to use Awiqli®.
- If you are taking pioglitazone with Awiqli®, contact your doctor if you have any signs or symptoms of congestive heart failure (when the heart does not pump blood as well as it should) such as shortness of breath, tiredness, fluid retention, weight gain and swelling around ankles.
- Eye problems – fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye retinopathy (an eye condition that can cause loss of vision and blindless in people who have diabetes). If you have eye problems, talk to your doctor.
- Make sure you use the right type and dose of insulin – always check the label on your insulin pen before each injection to avoid mix-ups with

other insulin products. If you use/have used another injectable once-weekly medication for diabetes, please pay particular attention, as the way you select a dose with Awiqli® pen differs from other once-weekly injectable medications. Always make sure that you select the correct dose on your Awiqli® pen as prescribed by your physician, to avoid dosing errors and accidental overdose. If you are blind or have poor vision, ensure that you get assistance from another person who has good vision and is trained in using the pre-filled pen.

- Never dial the maximum single dose (700 units) of your Awiqli® pen, unless this is your prescribed dose.

Skin changes where the injection is given
The injection site should be changed regularly to help prevent changes to the fatty tissue under the skin. Such changes include skin thickening or shrinking or lumps under the skin.

This medicine may not work properly if you inject into a lumpy, shrunken or thickened area (see How to use Awiqli®). Tell your doctor, pharmacists or nurse if you notice any skin changes where the injection is given and if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor, pharmacist or nurse may tell you to check your blood sugar more closely, and to adjust your dose of Awiqli® or other antidiabetic medicines dose if needed.

Antibodies to insulin
Treatment with Awiqli® can cause the body to produce antibodies to insulin (molecules that can affect treatment with insulin). This may very rarely, require you to change your insulin dose.

Children and adolescents
Do not give this medicine to children and adolescents between the ages of 0 and 18 years. This is because there is no experience with using Awiqli® in children or adolescents.

- ***Taking other medicines***

Other medicines and Awiqli®
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. Some medicines affect your blood sugar level, this may mean your dose of Awiqli® has to be changed.

Listed below are the most common medicines which may affect your treatment with Awiqli®.

You may need a lower dose / your blood sugar level may fall (hypoglycaemia) if you take:

- other medicines for diabetes (by mouth or injection)
- sulfonamides, for infections
- anabolic steroids, such as testosterone
- beta-blockers for high blood pressure. They may make it harder to recognise the warning signs of too low blood sugar (see information in the box at the end of this leaflet. Warning signs of too low blood sugar)
- acetylsalicylic acid (and other salicylates), for pain and mild fever
- monoamine oxidase (MAO) inhibitors, for depression
- angiotensin converting enzyme (ACE) inhibitors, for some heart problems or high blood pressure.

You may need a higher dose / your blood sugar level may rise (hyperglycaemia) if you take:

- danazol, for endometriosis
- oral contraceptives (birth control pills)
- thyroid hormones, for thyroid problems
- growth hormone, for growth hormone deficiency
- glucocorticoids such as cortisone, for inflammation
- sympathomimetics such as epinephrine (adrenaline), salbutamol or terbutaline, for asthma
- thiazides, for high blood pressure or if your body keeps too much water (water retention).

Octreotide and lanreotide (for a rare illness involving too much growth hormone (acromegaly)) may increase or decrease your blood sugar level.

Pioglitazone (a diabetes medicine given by mouth for type 2 diabetes). Some patients with long-standing type 2 diabetes and heart disease or previous stroke treated with pioglitazone and insulin developed heart failure.

- Tell your doctor straight away if you have signs of heart failure – such as shortness of breath, tiredness, fluid retention, weight gain and swelling around ankles.

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before injecting Awiqli® as the adjustment of the dose of a weekly insulin in relation to interaction with other medicines may be different.

How to use Awiqli®
Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Awiqli® is given **once a week.**

Awiqli® is a long-acting insulin. It can be used with short or rapid-acting insulins.

In type 2 diabetes:
- Awiqli® may be used along with tablets or injections for diabetes - including short or rapid-acting insulins.

In type 1 diabetes:
- Awiqli® must always be used along with short or rapid-acting insulins.
- If you are newly diagnosed with type 1 diabetes (you are not on insulin treatment already), Awiqli® is not suitable for you.

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 pre-filled pen.

What the pens contain
The pre-filled pen can provide a dose of 10-700 units in one injection in steps of 10 units.
- Awiqli 700 units/mL (1 mL) contains 700 units
- Awiqli 700 units/mL (1.5 mL) contains 1 050 units
- Awiqli 700 units/mL (3 mL) contains 2 100 units

The dose counter of the pre-filled pen shows the number of units of insulin you should inject. For this reason, do not make any dose recalculation. The pre-filled pen 700 units/mL can provide a dose of 10-700 units in one injection in steps of 10 units.

How to inject
- Inject Awiqli® under the skin (subcutaneous injection). Do not inject it into a vein or muscle.
- The best places to inject are your thighs, upper arms or your belly (abdomen).
- Change the place where you inject this medicine each time. This is to reduce the risk of developing lumps and skin pitting (see Before you use Awiqli®).
- Always use a new needle for each injection. This reduces the risk of contamination, infection, and blocked needles that may lead to inaccurate dosing. Dispose of needles safely after each use.
- Do not use a syringe to remove the solution from the pen - to avoid dosing errors and potential overdose.

Detailed instructions for use are provided on the end of this leaflet.

- ***How much to use***

Your doctor will decide together with you:
- how much Awiqli® you will need each week
- when to check your blood sugar level
- when you need a higher or lower dose - as your doctor may change your dose based on your blood sugar level
- if your treatment needs to be adjusted when using other medicines.

- ***When to use it***

Awiqli® is a basal insulin for use **once a week**.
- You should inject Awiqli® on the same day every week.
- You can take the medicine at any time of the day.

Dose when switching from a once- or twice-daily basal insulin
Your once a week dose of Awiqli® depends on your current basal insulin dose. Your doctor will prescribe you the dose that covers your weekly basal insulin need.

- For the first injection only, you may need to take an increased Awiqli® dose. This dose is for the first injection only; do not use this dose for the second and following injections. Please talk to your doctor about how much you should take for your first injection.
- Your dose should be based on your blood glucose measurements. Your doctor will decide together with you how much Awiqli® you will have each week.
- Close glucose monitoring is recommended during the switch and in the following weeks.

Use in the elderly (65 years and older)
Awiqli® can be used in the elderly.

If you have kidney or liver problems
If you have kidney or liver problems, you may need to check your blood sugar level more often.

Before injecting Awiqli®
Before you use Awiqli® for the first time, read the instructions for use that come with this package. Check the name on the label of the pen to make sure it is Awiqli® 700 units/mL.

- ***How long to use it***

Do not stop using Awiqli® without talking to your doctor. If you stop using this medicine, this could lead to a very high blood sugar level (hyperglycaemia) and ketoacidosis (a condition with too much acid in the blood). See advice in the information in the box at the end of this leaflet - Too high blood sugar (hyperglycaemia).

- ***If you forget to use it***

If you are a type 1 diabetes patient
- Inject it as soon as you remember. You should then inject Awiqli® one week after you have injected the missed dose. This day will become your new weekly injection day for Awiqli®. Continue injecting once a week afterwards.
- If you wish to return to your usual injection day, you may do so in agreement with your doctor by extending the time between your next doses.
- If you are unsure when to take

your medicine, talk to your doctor or pharmacist.

If you are a type 2 diabetes patient

- If it is 3 days or less after you should have injected Awiqli®, inject it as soon as you remember. Then inject your next dose on your usual injection day.
- If it is more than 3 days since you should have injected Awiqli®, inject it as soon as you remember. You should inject your next dose of Awiqli® one week after you have injected the missed dose. If you wish to return to your usual injection day, you may do so in agreement with your doctor by extending the time between your next doses.
- Continue injecting once a week afterwards.
- If you are unsure when to take your medicine, talk to your doctor or pharmacist.

- ***If you use too much (overdose)***

If you use too much of this medicine, your blood sugar may get too low (hypoglycaemia). See guidance in the information in the box at the end of this leaflet – Too low blood sugar (hypoglycaemia).

While you are using Awiqli®

- ***Things you must do***

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

Tell all the doctors, dentists and pharmacists treating you that you are using Awiqli®.

Tell your doctor immediately if you become pregnant while using this medication.

Take Awiqli® only with a doctor's prescription.

- ***Things you must not do***

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Awiqli® to anyone else, even if they have the same symptoms or condition as you.

You should not use Awiqli®

- in insulin infusion pumps
- if the pen is damaged or has not been stored correctly (see Storage and Disposal of Awiqli®)
- if there are visible particles - the solution should be clear and colourless.

- ***Things to be careful of***

Awiqli® with alcohol

If you drink alcohol, the dose of Awiqli® you need may change. Your blood sugar level may either rise or fall. This means you need to check your blood sugar level more often than usual when you drink alcohol.

Pregnancy and breast-feeding

It is not known if or how Awiqli® may affect a foetus. Therefore, you should stop the treatment with this medicine if you are a woman of childbearing potential trying to conceive. If you get pregnant while using this medicine, contact your doctor for guidance.

It is not known if this medicine is excreted in human milk and a risk for the baby cannot be excluded. Therefore, Awiqli® should not be used while breast-feeding and it must be decided if you should stop the treatment with this medicine or if you should avoid breast-feeding.

Driving and using machines

Awiqli® has no or negligible effects on the ability to drive and use machines, but it changes your blood sugar levels. Having too low or too high blood sugar can affect your ability to drive or use any tools or machines. If your blood sugar is too low or too high, your ability to concentrate or react might be affected. This could be dangerous to yourself or others. Ask your doctor or nurse for guidance if:

- you often get too low blood sugar
- you find it hard to recognise too low blood sugar.

Important information about some of the ingredients of Awiqli®

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e., it is essentially 'sodium-free'.

Side effects

Like all medicines, Awiqli® can cause side effects, although not everybody gets them.

Possible side effects are:

Hypoglycaemia (too low blood sugar) – very common (may affect more than 1 in 10 people)

- It can be very serious
- If your blood sugar level falls too much, you may pass out.
- Serious hypoglycaemia may cause brain damage and may be life-threatening.

If you have signs of low blood sugar, try to increase your blood sugar level straight away. See advice in 'Too low blood sugar (hypoglycaemia)' below.

Hypersensitivity reactions – uncommon (may affect up to 1 in 100 people)

The signs of a serious allergic reaction are:

- feeling unwell (light-headed)
- difficulty breathing
- fast heartbeat or feeling dizzy
- nausea and vomiting
- local reactions such as rash, swelling, or itching that spread to other parts of your body
- sweating and loss of consciousness.

If you have a serious allergic reaction to Awiqli®, stop using this medicine and see a doctor straight away. Serious allergic reaction can be life threatening if throat swelling

blocks the airway.

Skin changes where the injection is given – rare (may affect up to 1 in 1 000 people)

- If you inject this medicine too often at the same place, the skin may shrink (lipoatrophy) or thicken (lipohypertrophy).
- Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis) if you often inject your insulin at the same place. How often this occurs is not known.
- This medicine may not work very well if you inject into a lumpy, shrunken or thickened area.
- Change the injection site with each injection to help prevent these skin changes.

Other side effects include:
Common (may affect up to 1 in 10 people)

- Skin problems where the injection is given such as bruising, bleeding, pain or discomfort, redness, swelling, itching.
- Peripheral oedema (swelling especially around the ankles and feet due to fluid retention).

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. By reporting side effects you can help provide more information on the safety of this medicine.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my *[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]*

Storage and Disposal of Awiqli®

- ***Storage***

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 'Expiry'. The expiry date refers to the last day of that month.

Before first use
Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep away from the freezing element.

Keep the cap on the pen in order to protect it from light.

After first opening or if carried as a spare
You can carry your Awiqli® pre-filled pen (FlexTouch®) with you and keep it at room temperature (below 30 °C) or in a refrigerator (2 °C - 8 °C) for up to 12 weeks.

Always keep the cap on the pen when you are not using it in order to protect it from light.

- ***Disposal***

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- ***What it looks like***

Awiqli® is presented as a clear and colourless solution for injection in a pre-filled pen.

The outer packaging is in green with the strength '700 units/mL' indicated in a yellow-coloured box. The pen body is in green while the pen label is in darker green with a yellow box highlighting the formulation strength.

- ***Pack sizes***

Awiqli® pre-filled pen containing 700 units of insulin icodec in 1 mL solution.

- 1 pre-filled pen (without needles).
- 1 pre-filled pen with 9 disposable NovoFine® Plus needles.
- 1 pre-filled pen with 14 disposable NovoFine® Plus needles.

Awiqli® pre-filled pen containing 1 050 units of insulin icodec in 1.5 mL solution.

- 1 pre-filled pen (without needles).
- 1 pre-filled pen with 13 disposable NovoFine® Plus needles.
- 1 pre-filled pen with 14 disposable NovoFine® Plus needles.

Awiqli® pre-filled pen containing 2 100 units of insulin icodec in 3 mL solution.

- 1 pre-filled pen (without needles).
- 1 pre-filled pen with 13 disposable NovoFine® Plus needles.
- 1 pre-filled pen with 14 disposable NovoFine® Plus needles.

Not all pack sizes may be marketed.

Ingredients

- *Active ingredient*

The active substance is insulin icodec. Each mL of solution contains 700 units of insulin icodec. Each pre-filled pen contains 700, 1 050 or 2 100 units of insulin icodec in 1, 1.5 or 3 mL solution, respectively.

- *Inactive ingredients*

The other ingredients are glycerol, metacresol, phenol, zinc acetate, sodium chloride, hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injections.

- ***MAL number***

MALXXXXXXXXAZ

Manufacturer

Manufactured by:
Novo Nordisk A/S
Brennum Park 1
DK-3400 Hilleroed
Denmark

Released by:
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HYPERGLYCAEMIA AND HYPOGLYCAEMIA

General effects from diabetes treatment
Too low blood sugar (hypoglycaemia)
This may happen if you:
- drink alcohol
- use too much insulin
- exercise more than usual
- eat too little or miss a meal.

Warning signs of too low blood sugar - these may come on suddenly:
- headache
- fast heartbeat
- feeling sick or very hungry
- cold sweat or cool pale skin
- short-lasting changes in your sight
- tremor or feeling nervous or worried
- feeling unusually tired, weak and sleepy
- slurred speech, feeling confused, difficulty in concentrating.

What to do if you get too low blood sugar:
- Eat glucose tablets or another high sugar snack, like sweets, biscuits or fruit juice (always carry glucose tablets or a high sugar snack, just in case).
- Measure your blood sugar if possible and rest. You may need to measure your blood sugar more than once. This is because with basal insulins like Awiqli®, the increase in blood sugar may be delayed.
- Then wait until the signs of too low blood sugar have gone or when your blood sugar level has settled. Then carry on with your insulin as usual.
- If you have type 1 diabetes and experience multiple episodes of too low blood sugar, you should consult your doctor.

What others need to do if you pass out
Tell everyone you spend time with that you have diabetes. Tell them what could happen if your blood sugar gets too low, including the risk of passing out.

Let them know that if you pass out, they must:
- turn you on your side
- get medical help straight away
- **not** give you any food or drink because you may choke.

You may recover more quickly from passing out with administration of glucagon. This can only be given by someone who knows how to use it.
- If you are given glucagon, you will need sugar or a sugary snack as soon as you come round.
- If you do not respond to glucagon, you will have to be treated in a hospital.

If severe low blood sugar is not treated over time, it can cause brain damage. This can be short or long-lasting. It may even cause death.

Talk to your doctor if:
- your blood sugar got so low that you passed out
- you have used glucagon
- you have had too low blood sugar a few times recently.

This is because the dosing of your insulin injections, food or exercise may need to be changed.

Too high blood sugar (hyperglycaemia)
This may happen if you:
- drink alcohol
- get an infection or a fever
- have not used enough insulin
- eat more or exercise less than usual
- keep using less insulin than you need
- forget to use your insulin or stop using insulin without talking to your doctor.

Warning signs of too high blood sugar - these normally appear gradually:
- feeling thirsty
- flushed or dry skin
- losing your appetite
- feeling sleepy or tired
- passing water more often
- dry mouth or fruity (acetone) breath
- feeling or being sick (nausea or vomiting).

These may be signs of a very serious condition called ketoacidosis. This is a build-up of acid in the blood because the body is breaking down fat instead of sugar. If not treated, this could lead to diabetic coma and eventually death.

What to do if you get too high blood sugar:
- test your blood sugar level.
- test your urine or blood for ketones.
- get medical help straight away.

Instructions for use

Before you begin using your needle and Awiqli® pen, **always read these instructions carefully,** and talk to your doctor, nurse or pharmacist about how to inject Awiqli® correctly.

Awiqli® pen is a pre-filled disposable pen containing insulin icodec 700 units/mL. You can inject from 10 to 700 units in a single once-weekly injection.

Always start by checking your pen label to make sure that it contains Awiqli® 700 units/mL.

Your pen is designed to be used with NovoFine® Plus or NovoFine® disposable needles up to a length of 8 mm.

Once-weekly injection

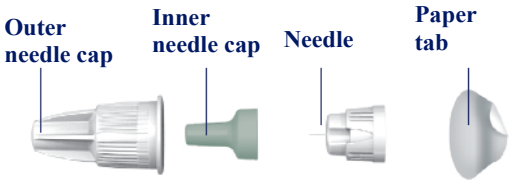
Awiqli® pen

Please note: Your pen may differ in size from the pen shown in the picture. These instructions apply to all Awiqli® pens.

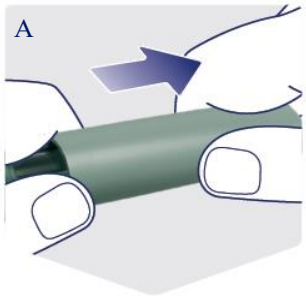
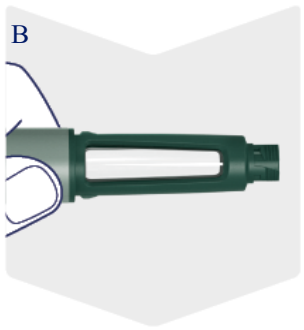
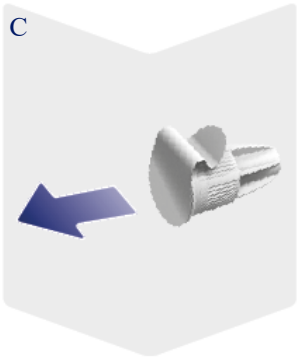
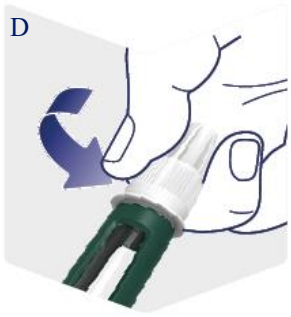
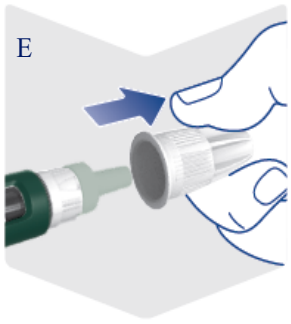
About your needles

Always use a new needle for each injection. Check the flow as described in 'Step 2' and use a new needle for each injection. Always remove the needle after each use.

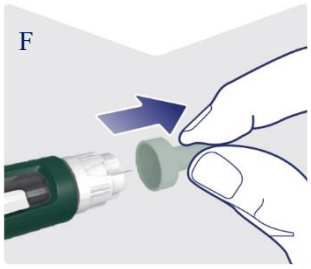
NovoFine® Plus Needle (example)



Step 1 Prepare your pen with a new needle

• **Check the name and concentration on the pen label** to make sure that your pen contains insulin icodec 700 units/mL. • Pull off the pen cap. See Figure A.	
• **Always check that the insulin in your pen is clear and colourless.** • Look through the pen window. If the insulin looks cloudy or contains particles, do not use the pen. See Figure B.	
• **Always use a new needle for each injection.** • Check the paper tab and outer needle cap for damages. If you see any damage, this could affect sterility. Throw out the needle and use a new one. • Take a new needle and tear off the paper tab. • **Do not attach a new needle to your pen until you are ready to give your injection.** See Figure C.	
• **Push the needle straight onto the pen. Turn until it is on tight.** See Figure D. • **The needle is covered by two caps. You must remove both caps.** If you forget to remove both caps, you will not inject any Awiqli®.	
• Pull off the outer needle cap and keep it for later. You will need it to safely remove the needle from the pen after the injection. See Figure E. • **Pull off the inner needle cap and throw it away.** See Figure F. • A drop of Awiqli® may appear at the needle tip. This is normal, but you must still check the Awiqli® flow before each injection. See 'Step 2'. • **Never use a bent or damaged needle.**	

F

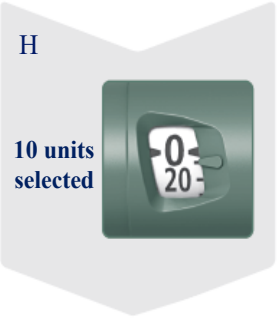


Step 2 Check the flow before each injection

- **Always check the flow before each injection.** This helps you to ensure you will get your full Awiqli® dose.
- Turn the dose selector clockwise until you see the first mark (10 units) on the dose counter. See Figure G.
- Make sure that the mark lines up with the dose pointer. See Figure H.

G

H



- Hold the pen with the needle pointing up.
- **Press and hold in the dose button until the dose counter shows** -0-. The -0- must line up with the dose pointer.
- A drop of Awiqli® should appear at the needle tip. This drop indicates that your pen is ready for use. See Figure I.
- **If a drop does not appear, check the flow again.** This should only be done six times in total.
- **If there is still no drop,** you might have a blocked needle. Change the needle as described in **'Step 5' and 'Step 1'.**
- Then check the flow once more.
- **Do not use the pen** if a drop of Awiqli® still does not appear.

I

Step 3 Set your dose

- Check that the dose pointer is set at -0-. See Figure J.
- Turn the dose selector to select the number of units you need to inject as directed by your nurse or doctor. The dose counter shows the dose dialled in units.
- **Make sure you select your intended dose.**

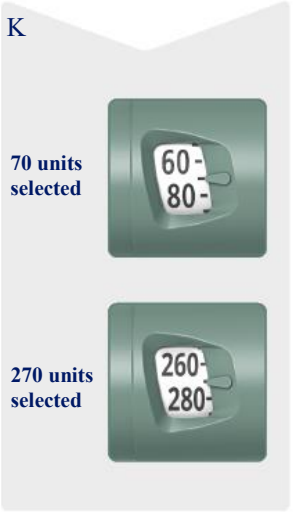
J

- The units shown in the dose counter will guide you to your dose. The dose can be increased by **10 units** at a time.
- You will hear a 'click' every time you turn the dose selector. Do not set the dose by counting the number of clicks you hear.
- If you select a wrong dose, you can turn the dose selector forwards or backwards to the correct dose.

- When your dose lines up with the dose pointer, you have selected your dose. **Make sure you select your intended dose.**

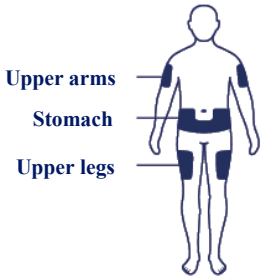
- The pictures show examples of how to choose your dose correctly. See Figure K.
- If the dose counter stops before you reach your prescribed dose, see the section **'Do you have enough Awiqli®?'** below these instructions.

K



Choose your injection site

- Choose an injection site on your stomach (keep a 5 cm distance from your belly button), upper legs, or upper arms.
- You may inject in the same body area each week, but make sure it is not in the same spot that was used for your last injection.

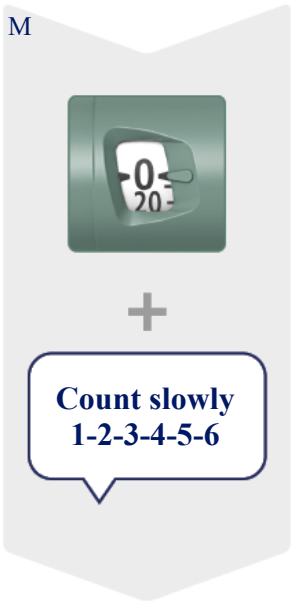
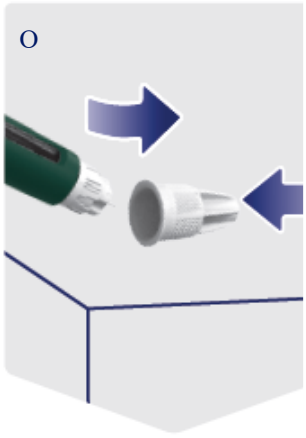


Step 4 Inject your dose

- Fully insert the needle into your skin. See Figure L.
- Make sure you can see the dose counter. **Do not cover the dose counter or touch it with your fingers.** This could stop the injection.

L

- **Press and hold down the dose button until the dose counter shows 0 .**
- **Continue pressing the dose button with the needle in your skin and slowly count to 6.** The 0 must line up with the dose pointer. See Figure M. You may hear or feel a click when the dose counter returns to 0 .

	M 
• Remove the needle from your skin, you can then release the dose button. See Figure N. • If the needle is removed earlier, a stream of Awiqli® might come from the needle tip and the full dose will not be delivered. • If blood appears at the injection site, press lightly on the area to stop the bleeding. • You may see a drop of Awiqli® at the needle tip after injecting. This is normal and does not affect your dose.	N 
Step 5 After your injection	
• Carefully insert the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap. See Figure O. • Once the needle is covered, carefully push the outer needle cap completely on.	O 

- Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist or local authorities. See Figure P.
- Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.
- **Always remove and dispose of the needle immediately after each injection** to prevent contamination, infection, blocked needles and inaccurate dosing.
- Never store your pen with the needle attached**.**

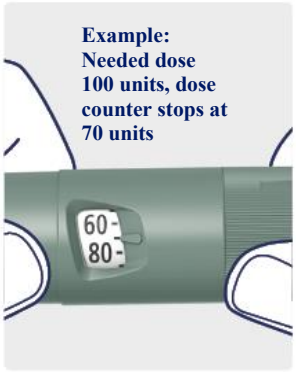
P

- **Put the pen cap on** your pen after each use to protect Awiqli® from light. See Figure Q.
- When the pen is empty, dispose of the pen without a needle on as instructed by your doctor, nurse, pharmacist or local authorities.
- The leaflet and the empty carton can be disposed of in your household waste.

Q

Do you have enough Awiqli®?

- If the dose counter stops before you reach your dose, there is not enough Awiqli® left for a full dose. The number shown in the dose counter is the number of units left in your pen.
- **If you need more Awiqli® than what is left in your pen**, you can split your dose between two pens. Be sure that you calculate correctly if you are splitting your dose. If you are in doubt, dispose of the used pen and take the full dose with a new pen.
- **If you split the dose incorrectly, you will inject too little or too much Awiqli®, which can lead to too high or too low blood sugar level.**



Important information

- **Needles are for single-use only. Never reuse your needles.** This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.
- **Treat your pen with care.** Rough handling or misuse may cause inaccurate dosing, which can lead to too high or too low blood sugar level.
- **Caregivers must be very careful when handling needles** to prevent accidental needle stick injuries and infection.
- **Do not use this pen without help if you have poor eyesight and cannot follow these instructions.** Get help from a person with good eyesight who is trained to use the Awiqli® pen.
- **Always keep pen, and needles out of sight and reach of others, especially children.**
- **Inject Awiqli® once weekly.**
- **Use your Awiqli® as prescribed. If you do not use your Awiqli® as prescribed, this can lead to too high or too low blood sugar level.**
- **If you use more than one type of injectable medicine, it is very important to check the name and concentration of your pen label before use.**
- **Never share** your pen or your needles with other people.

Caring for your pen

- Do not freeze Awiqli®. Do not use Awiqli® if it has been frozen. Dispose of the pen.
- Do not drop your pen or knock it against hard surfaces.
- Avoid exposing Awiqli® to direct sunlight.
- Keep Awiqli® away from heat, microwaves and out of the light.
- Do not try to repair your pen or pull it apart.
- 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.
- See Storage and Disposal of Awiqli® of this leaflet to read the storage conditions for your pen**.**