PATIENT INFORMATION LEAFLET

GILIPTRA

SCHEDULING STATUS: S4

GILIPTRA 6 mg / mL, solution for injection in pre-filled pen

Liraglutide

Sugar free

Preservative: Phenol 0,55 % *w/v*

Read all of this leaflet carefully before you start using GILIPTRA.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse, or other health care provider.
- GILIPTRA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

VP

1. What GILIPTRA is and what it is used for

- GILIPTRA contains a medicine called liraglutide which reduces your blood sugar level when blood sugar is too high.
- GILIPTRA is indicated as an adjunct to diet and exercise to achieve glycaemic control for the treatment of the type of diabetes called 'type 2 diabetes mellitus'.
- GILIPTRA is indicated for once-daily administration as:
    - Monotherapy
    - combination therapy with one or more oral antidiabetic medicines (metformin, sulphonylureas, sodium-glucose cotransporter 2 inhibitor (SGLT2i) or a thiazolidinedione) when previous therapy does not achieve adequate glycaemic control.
    - Combination therapy with insulin in patients not achieving adequate glycaemic control with GILIPTRA and metformin.

2. What you need to know before you use GILIPTRA

Do not use GILIPTRA

- if you have type 1 diabetes mellitus (your body does not produce any insulin).
- if you are hypersensitive (allergic) to liraglutide or any of the other ingredients of GILIPTRA (listed in **section 6**)
- if you are pregnant or intend to become pregnant or breastfeeding.
- if you previously had an inflammation of the pancreas.

Warnings and precautions

Take special care with GILIPTRA:

- if you have or have had a disease of the pancreas (inflammation of the pancreas).

  If you have thyroid disease including thyroid nodules and enlargement of the thyroid gland.

- If you have severe kidney disease or are on dialysis.
- There is no experience with GILIPTRA in patients with severe kidney problems.
- The use of GILIPTRA is not recommended if you have severe heart failure.
- GILIPTRA is not recommended if you have a severe stomach or gut problem which results in delayed stomach emptying (called gastroparesis), or inflammatory bowel disease.

  If you have symptoms of acute pancreatitis, such as persistent, severe stomach-ache, you should tell your doctor or healthcare professional immediately.
- When initiating treatment with GILIPTRA, you may experience loss of fluids/dehydration, e.g., in case of vomiting, nausea and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids. Tell your doctor or healthcare professional if you have any questions or concerns.

Children and adolescents

GILIPTRA is not recommended for children and young people under 18 years.

Other medicines and GILIPTRA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines) as using GILIPTRA at the same time with another medicine may cause undesirable interactions.

In particular, tell your doctor or pharmacist if you are using any of the following medicines for diabetes:

- Insulin.
- A sulphonylurea medicine (such as glimepiride or glibenclamide). This is because using GILIPTRA at the same time may cause your blood sugar to get too low (hypoglycaemia).
- When you first start using these medicines together, your doctor may tell you to lower the dose of the sulphonylurea medicine.

- If you are not sure if the medicines you are taking contain a sulphonylurea, ask your doctor or pharmacist.

GILIPTRA with food, drink, and alcohol

You can use GILIPTRA at any time of the day. It does not matter when you take it in relation to meals.

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using GILIPTRA.
- GILIPTRA is contraindicated in pregnancy and breastfeeding.
- You should not use GILIPTRA if you are pregnant or breastfeeding your baby.

  If you are being treated with GILIPTRA, you should not breastfeed your baby.

- If you are pregnant or breastfeeding your baby while using GILIPTRA please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machines

- GILIPTRA is not likely to affect your ability to drive or use any tools or machines.

  While you are driving or using tools or machines, you should avoid getting low blood sugar (hypoglycaemia). Your doctor will tell you how to do this.
- It is not always possible to predict to what extent GILIPTRA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GILIPTRA affects them.

GILIPTRA contains:

GILIPTRA contains less than 1 mmol sodium (23 mg) per dose, therefore the medicinal product is essentially 'sodium-free'. (see **section 6.1)**

3. How to use GILIPTRA

Do not share medicines prescribed for you with any other person.

Always use GILIPTRA exactly as your doctor or pharmacist has told you to. You should check with your doctor or pharmacist if you are not sure.

The GILIPTRA pen

GILIPTRA is a pen which is used to inject doses of 0,6 mg, 1,2 mg or 1,8 mg once a day.

- Each pen contains more than one dose, so it can be used more than once.
- Do not share your pen with anyone else.

Injection needles

- Injection needles are not included with GILIPTRA.
- GILIPTRA is designed to be used with NovoFine™ or BD UltraFine™ injection needles, up to a length of 8 mm and as thin as 32 G.
- Ask your doctor or diabetes nurse which injection needle width (gauge) and length is best for you.
- Use a new injection needle for each injection and dispose of it after use.

Using GILIPTRA

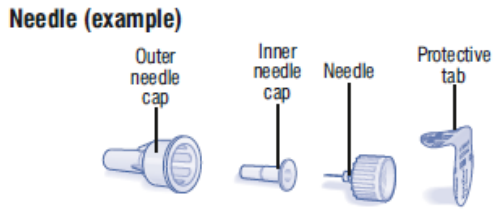
- GILIPTRA is an injection which is given under the skin (subcutaneously).
- Do not inject it into a vein or muscle.

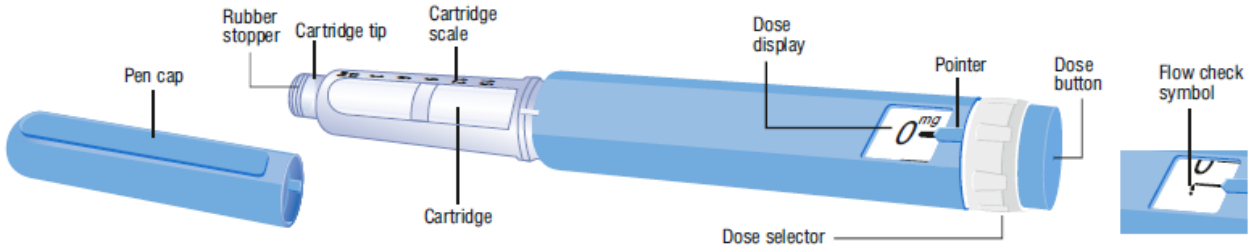
- The best places to give yourself the injection are the front of your thighs, the front of your waist (abdomen) or your upper arm.
- Change the place within the area where you inject each day to reduce the risk of developing lumps under the skin (see **section 4 'Possible side effects'**). You can give yourself the injection at any time of the day.
- Before you use the pen for the first time, your doctor or nurse will show you how to use it. *Detailed instructions for use are provided below:*

INSTRUCTIONS FOR USING THE PEN
Please read these instructions carefully before using your pen.

Your pen comes with 18 mg of liraglutide. You can select doses of 0,6 mg, 1,2 mg and 1,8 mg.

The pen is designed to be used with disposable injection needles up to a length of 8 mm and as thin as 32G (0,25/0,23 mm).

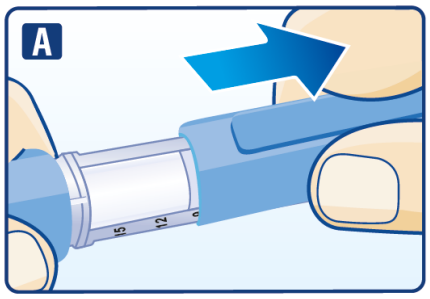


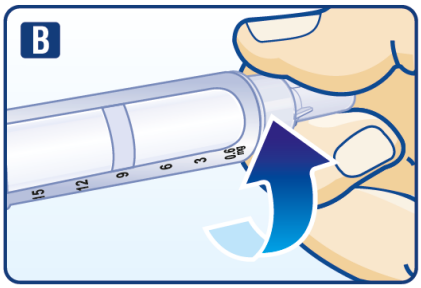
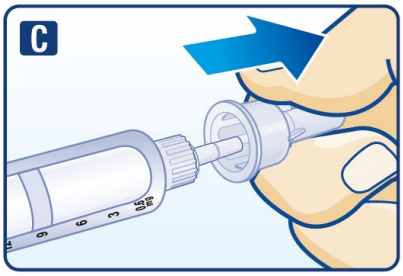
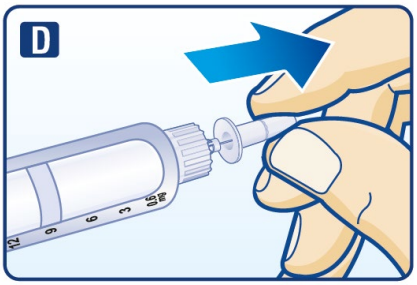


Prepare your pen

Check the name and coloured label of your pen to make sure that it contains liraglutide. Using the wrong medicine could cause severe harm.

Pull off the pen cap.



Pull off the paper tab from a new disposable needle. Screw the needle straight and tightly onto your pen.	
Pull off the outer needle cap and keep it for later.	
Pull off the inner needle cap and dispose of it.	

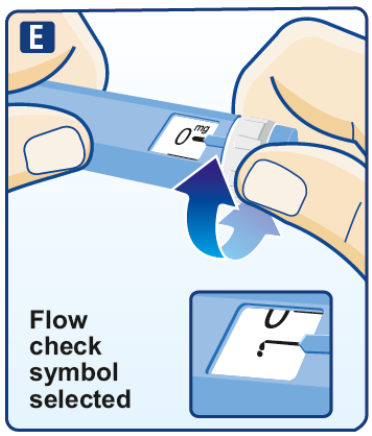
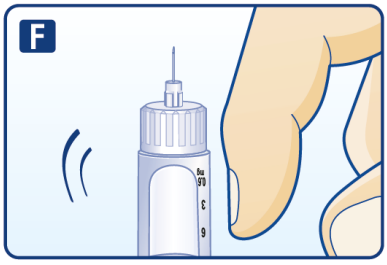
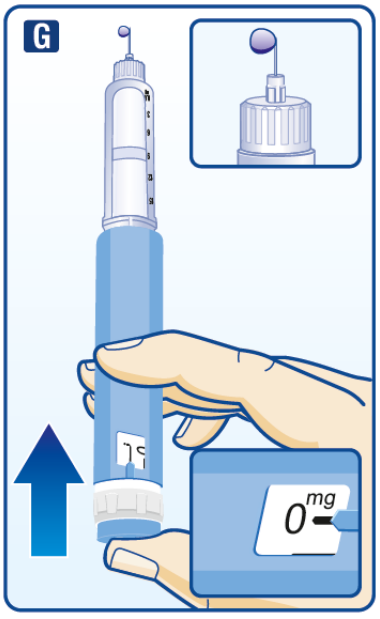
- ⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing.
- ⚠ Be careful not to bend or damage the needle.
- ⚠ Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

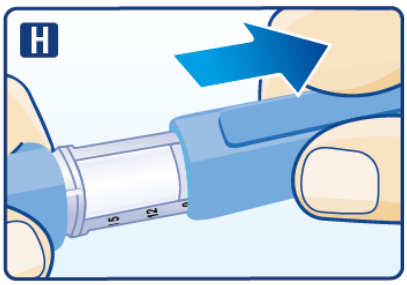
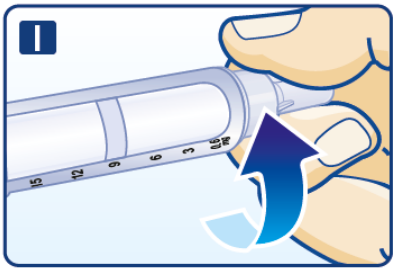
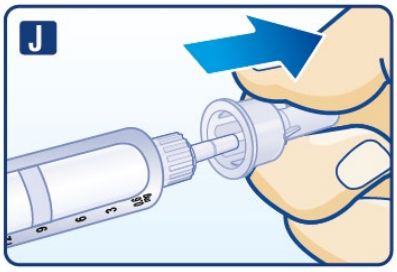
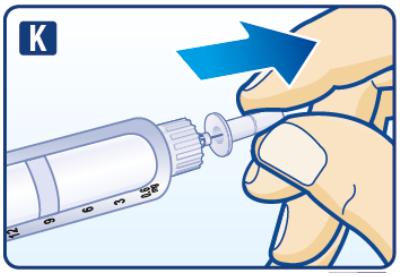
Caring for your pen

- Do not try to repair your pen or pull it apart.
- Keep your pen away from dust, dirt and all kinds of liquids.
- Clean the pen with a cloth moistened with a mild detergent.
- Do not try to wash, soak or lubricate it – this can harm the pen.

⚠ **Important information**

- Do not share your pen or needles with anyone else.
- Keep your pen out of the reach of others, especially children.

With each new pen, check the flow **Check the flow before your first injection with each new pen. If your pen is already in use, go to 'Select your dose', step L.** Turn the dose selector until the flow check symbol lines up with the pointer.	
Hold the pen with the needle pointing up. Tap the cartridge gently with your finger a few times. This will make any air bubbles collect at the top of the cartridge.	
Keep the needle pointing up and press the dose button until 0 mg lines up with the pointer. A drop of liraglutide should appear at the needle tip. If no drop appears, repeat steps E to G up to four times. If there is still no drop of liraglutide, change the needle and repeat steps E to G once more. Do not use the pen if a drop of liraglutide still does not appear. This indicates the pen is defective and you must use a new one.	
▲ If you have dropped your pen against a hard surface or suspect that something is wrong with it, always put on a new disposable needle and check the flow before you inject.	

Pull off the pen cap. **Check the name and coloured label** of your pen, to make sure that it contains Liraglutide 6 mg/mL solution for injection.	
Attach the Needle Remove protective tab from outer needle cap. • Push outer needle cap containing the needle straight onto the pen, then screw needle on until secure (See Figure I).	
• Pull off outer needle cap. Do not throw away (See Figure J).	
• Pull off inner needle cap and throw away (See Figure K). A small drop of liquid may appear. This is normal.	

Select your dose

Always check that the pointer lines up with 0 mg.

Turn the dose selector until your needed dose lines up with the pointer (0,6 mg, 1,2 mg or 1,8 mg).

If you selected a wrong dose by mistake, simply change it by turning the dose selector backwards or forwards until the right dose lines up with the pointer.

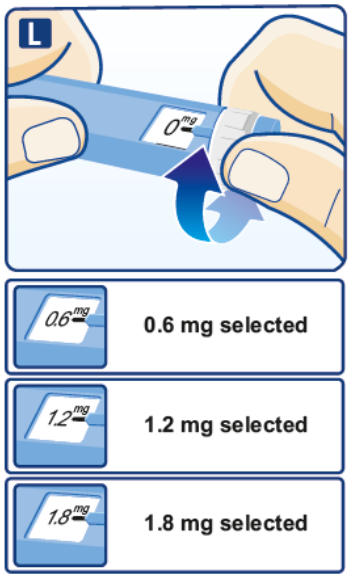
Be careful not to press the dose button when turning the dose selector backwards, as liraglutide may come out.

If the dose selector stops before your needed dose lines up with the pointer, there is not enough liraglutide left for a full dose. Then you can either:

Split your dose into two injections:
Turn the dose selector in either direction until 0,6 mg or 1,2 mg lines up with the pointer. Inject the dose. Then prepare a new pen for injection and inject the remaining number of mg to complete your dose.

You may only split your dose between your current pen and a new pen if trained or advised by your healthcare professional. Use a calculator to plan the doses. If you split the dose wrong, you may inject too much or too little liraglutide.

Inject the full dose with a new pen:
If the dose selector stops before 0,6 mg lines up with the pointer, prepare a new pen and inject the full dose with the new pen.



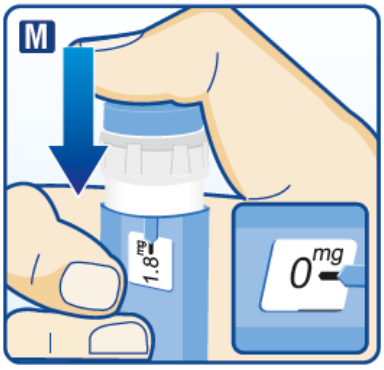
▲ Do not try to select other doses than 0,6 mg, 1,2 mg or 1,8 mg. The numbers in the display must line up precisely with the pointer to ensure that you get the correct dose. The dose selector clicks when you turn it. Do not use these clicks to select your dose. Do not use the cartridge scale to measure how much liraglutide to inject – it is not accurate enough.

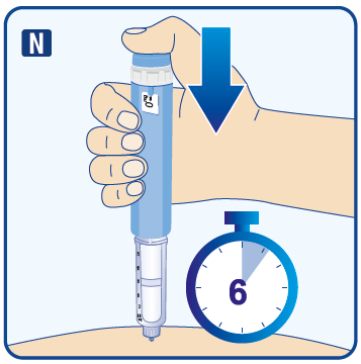
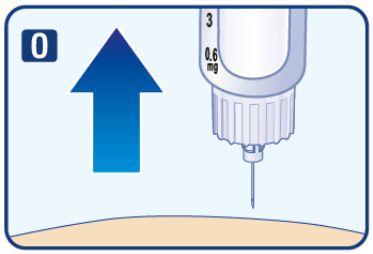
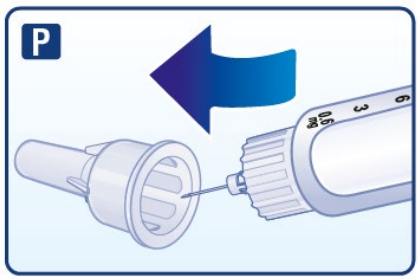
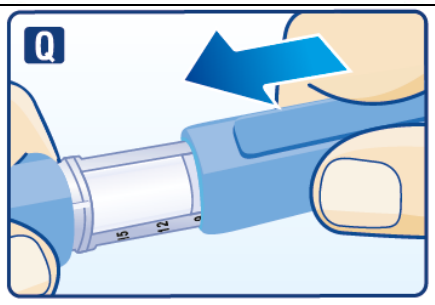
Inject your dose

Insert the needle into your skin using the injection technique shown by your doctor or nurse. Then follow the instructions below:

Press the dose button to inject until 0 mg lines up with the pointer. Be careful not to touch the display with your other fingers or press the dose selector sideways when you inject. This is because it may block the injection.

Keep the dose button pressed down and leave the needle under the skin for at least 6 seconds. This is to make sure



that you get your full dose.	
Keep the dose button pressed down and make sure that you keep the needle under the skin for a full count of 6 seconds to make sure the full dose is injected. Keep your thumb on the injection button until you remove the needle from your skin. Change (rotate) your injection sites within the area you choose for each dose. **Do not** use the same injection site for each injection.	
Pull out the needle. After that, you may see a drop liraglutide at the needle tip. This is normal and does not affect your dose.	
Guide the needle tip into the outer needle cap without touching the needle or the outer needle cap.	
When the needle is covered, carefully push the outer needle cap completely on. Then unscrew the needle. Dispose of it carefully and put the pen cap back on. When the pen is empty, carefully dispose of it without a needle attached. Please dispose of the pen and needle in accordance with local requirements.	
⚠ Always remove the needle after each injection, and store your pen without a needle attached. ⚠ This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing. ⚠ Caregivers must be very careful when handling used needles – to prevent needle injury and cross-infection.	

How much to inject.

- 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 will then be increased to 1,2 mg once a day. Do not change your dose unless your doctor has told you to. Do not use more than 1,8 mg per day.

Testing your blood sugar levels

- You will not need to test your blood sugar levels each day in order to adjust your dose of GILIPTRA.
- However, if you are taking a sulphonylurea medicine as well as GILIPTRA, your doctor may tell you to test your blood sugar levels to begin with. This will help your doctor to decide if the dose of the sulphonylurea needs to be changed.

If you use more GILIPTRA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.If you use too much of GILIPTRA, you may feel sick (have nausea) be sick (vomit) or experience low blood sugar (hypoglycaemia). Please refer to **section 4 'Possible side effects'** for early warning signs of low blood sugar.

If you forget to use a dose of GILIPTRA

- If you forget a dose, inject GILIPTRA as soon as you remember it.
- However, if it is more than 12 hours since you should have used GILIPTRA, skip the missed dose. Then take your next dose as usual on the following day.
- Do not administer a double dose or increase the dose on the following day to make up for forgotten individual doses.

If you stop using GILIPTRA

Do not stop administering GILIPTRA without telling your doctor. If you stop using it, your blood sugar levels may increase.

4. Possible side effects

GILIPTRA can have side effects.

Not all side effects reported for GILIPTRA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using GILIPTRA, please consult your health care provider for advice.

If the following happens, stop using GILIPTRA and tell your doctor immediately or go to the casualty department at your nearest hospital:

A severe form of allergic reaction (anaphylactic reaction) with additional symptoms such as breathing problems, swelling of throat and face, fast heartbeat, etc.

These are all very serious side effects. If you have them, you may have had a serious reaction to GILIPTRA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Feeling sick (nausea). This usually goes away over time,
- Diarrhoea,
- Headache,
- Being sick (vomiting),
- Burping,
- Indigestion,
- Inflamed stomach (gastritis). The signs include stomach pain, feeling sick (nausea) and being

- sick (vomiting),
- Gastro-oesophageal reflux disease (GORD), that includes heartburn,
- Painful or swollen tummy (abdomen),
- Constipation,
- Wind (flatulence),
- Anorexia,
- Decreased appetite,
- Infection of the upper airways,
- Low blood sugar (hypoglycaemia).

The warning signs of low blood sugar may come on suddenly and can include:

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

Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs.

If you are already taking a sulphonylurea medicine when you start using GILIPTRA, your doctor may tell you to reduce the dose of the sulphonylurea medicine.

Less frequent side effects:

- Pancreatitis (inflammation of the pancreas). Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking GILIPTRA and contact a doctor immediately if you notice any of the following serious side effects: severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis),
- Thyroid events - like nodules, increased blood calcitonin, goitres and cancer,
- increased pulse rate,
- urticaria (a type of rash),
- pruritus (itching),
- malaise (feeling unwell),
- dehydration, sometimes with a decrease in kidney function,
- injection site reactions (such as bruising, pain, irritation, itching and rash),
- Increased lipase (enzyme the body uses to break down fats in food so they can be absorbed in the intestines) / amylase (an enzyme that allows the body to change some substances into simple sugars),
- Fatigue (feeling tired),
- Cholelithiasis/Cholecystitis (Gallstones/inflamed gallbladder)

Side effects with unknown frequency:

- Lumps under the skin may be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). GILIPTRA may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent this skin change.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of GILIPTRA.

5. How to store GILIPTRA

- Store all medicines out of reach of children.
- Do not use GILIPTRA after the expiry date stated on the label and carton. The expiry date refers to the last day of that month.

Before you start to use GILIPTRA:

- Store it in a refrigerator between 2 °C and 8 °C away from the freezer compartment.

Do not freeze.

When GILIPTRA is being used:

- Keep for 1 month either at room temperature at or below 30 °C) or in a refrigerator between 2 °C and 8 °C.
- Do not use GILIPTRA if it has been frozen.
- Do not use GILIPTRA if it is not clear and colourless.
- Always remove the injection needle after each injection and store your GILIPTRA pen without an injection needle attached. This prevents contamination, infection, and leakage. It also ensures that the dosing is accurate.
- When you are not using the pen, keep the cap on. This will protect GILIPTRA from light.

- Protect GILIPTRA from high temperatures and sunlight.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GILIPTRA contains

The active substance in GILIPTRA is Liraglutide.

GILIPTRA contains:

Each pre-filled pen contains liraglutide 18 mg in 3 mL.

The other ingredients are disodium phosphate dihydrate, hydrochloric acid (for pH adjustment), phenol, propylene glycol, sodium hydroxide (for pH adjustment), and water for injection.

What GILIPTRA looks like and contents of the pack

GILIPTRA comes as a colourless or almost colourless liquid (solution for injection) in a glass cartridge inside a pen injector. The solution is not cloudy and does not contain any particles.

GILIPTRA is a sterile, aqueous, clear, colourless or almost colourless solution filled in a 3 mL glass cartridge and assembled into a single-patient use, disposable multi-dose pen-injector. Each pen-injector contains 3 mL of drug product at a concentration of 6 mg/mL. The delivered dose of each injection is 0,6 mg, 1,2 mg or 1,8 mg per dose depending on the setting of the multi-dose pen injector.

Each pen contains 3 mL of solution, delivering 30 doses of 0,6 mg, 15 doses of 1,2 mg or 10 doses of 1,8 mg.

Pack sizes of 2 or 3 pens are packed in a cardboard box.

Not all pack sizes may be marketed. Needles are not included.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

VP

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Parc du Cap

Mispel Street

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7530

Customer Care: 080 222 6662

This leaflet was last revised in

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Latest renewal: Not applicable

Revision: Not applicable

Registration number

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.

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