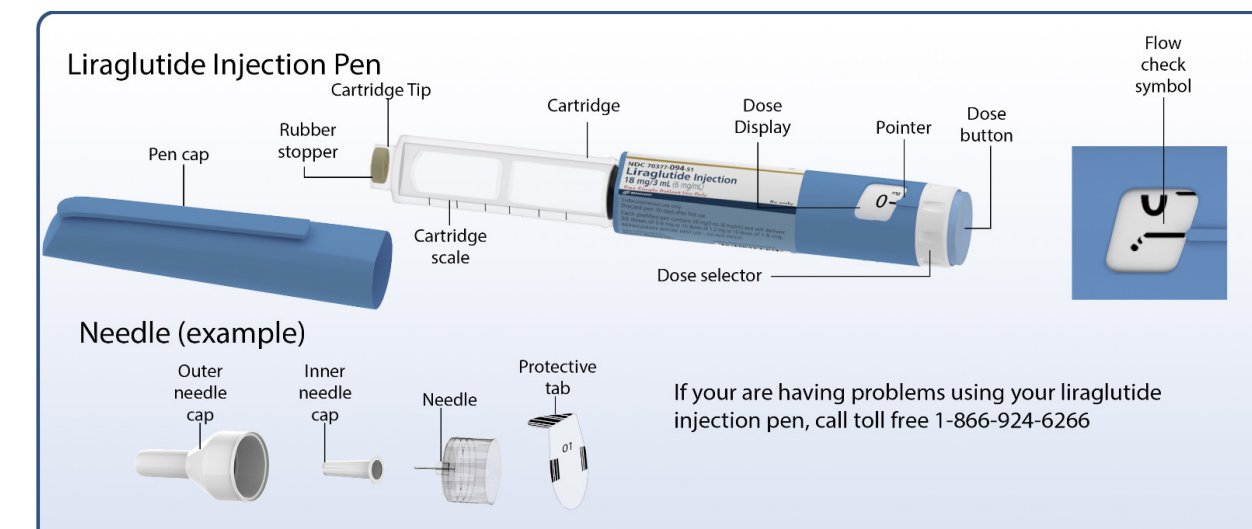


INSTRUCTIONS FOR USE

Liraglutide injection



First read the Medication Guide that comes with your liraglutide injection single-patient use pen and then read this Instructions for Use for information about how to use your liraglutide injection pen the right way.

These instructions do not take the place of talking with your healthcare provider about your medical condition or your treatment.

Do not share your liraglutide injection Pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Your liraglutide injection pen is a disposable single-patient-use prefilled pen injector that contains 3 mL of liraglutide injection and will deliver doses of 0.6 mg, 1.2 mg or 1.8 mg. The number of doses that you can take with a liraglutide injection pen depends on the dose of medicine that is prescribed for you. Your healthcare provider will tell you how much liraglutide injection to take.

Talk to your healthcare provider or pharmacist for more information about needles for your liraglutide injection pen.

Important Information

- △ Always use a new needle for each injection to prevent contamination.
- △ Always remove the needle after each injection, and store your pen without the needle attached. This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing.
- △ Keep your liraglutide injection pen and all medicines out of the reach of children.
- △ If you drop your liraglutide injection pen, repeat "First Time Use for Each New Pen" (steps A through D).
- △ Be careful not to bend or damage the needle.
- △ Do not use the cartridge scale to measure how much liraglutide to inject.
- △ Be careful when handling used needles to avoid needle stick injuries.
- △ You can use your liraglutide injection pen for up to 30 days after you use it the first time.

Supplies you will need to give your Liraglutide injection:

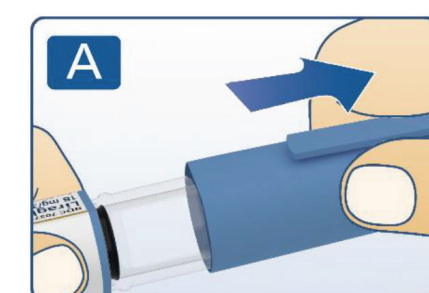
- Liraglutide injection pen
- a new disposable needle
- alcohol swab
- cotton ball or gauze
- sharps disposal container for throwing away used Liraglutide injection pens and needles.

See "Remove and Dispose of the Needle" at the end of these instructions.

First Time Use for Each New Pen

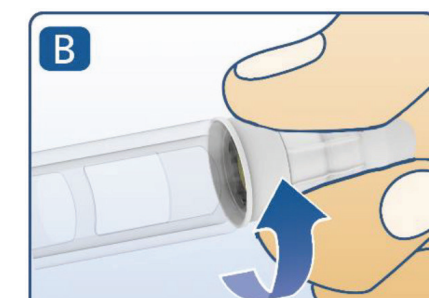
Step A. Check the Pen

- Take your new liraglutide injection pen out of the refrigerator.
- Wash hands with soap and water before use.
- Check pen label before each use to make sure it is your liraglutide injection pen.
- Pull off pen cap (See Figure A).
- Check liraglutide in the cartridge. The liquid should be clear, colorless and free of particles. If not, do not use.
- Wipe the rubber stopper with an alcohol swab.

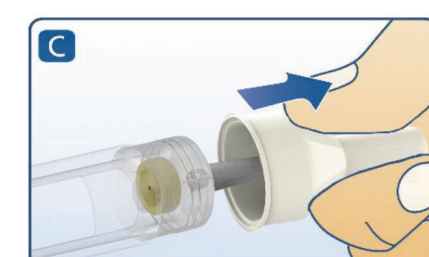


Step B. Attach the Needle

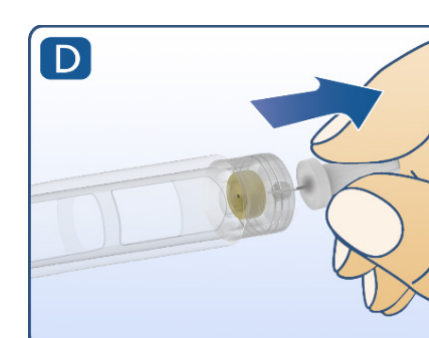
- Remove protective tab from outer needle cap.
- Push outer needle cap containing the needle straight onto the pen, then screw needle on until secure. (See Figure B).



- Pull off outer needle cap. (See Figure C). Do not throw away



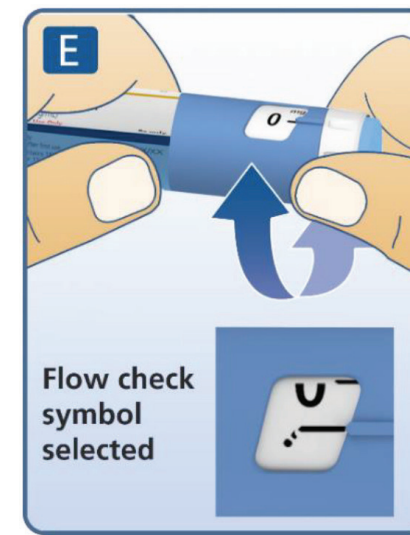
- Pull off inner needle cap and throw away. (See Figure D). A small drop of liquid may appear. This is normal.



Step C. Dial to the Flow Check Symbol

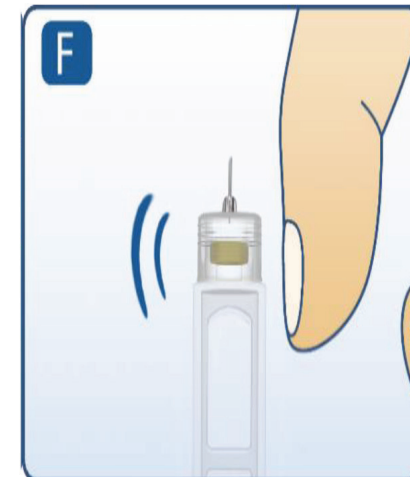
This step is done only **One Time** for each new pen and is **Only** required the first time you use a new pen.

- Turn dose selector until the black line of flow check symbol (✓) lines up with pointer (See Figure E). The flow check symbol does not administer the dose as prescribed by your healthcare provider.
- To select the dose prescribed by your healthcare provider, continue to **Step G** under "Routine Use".

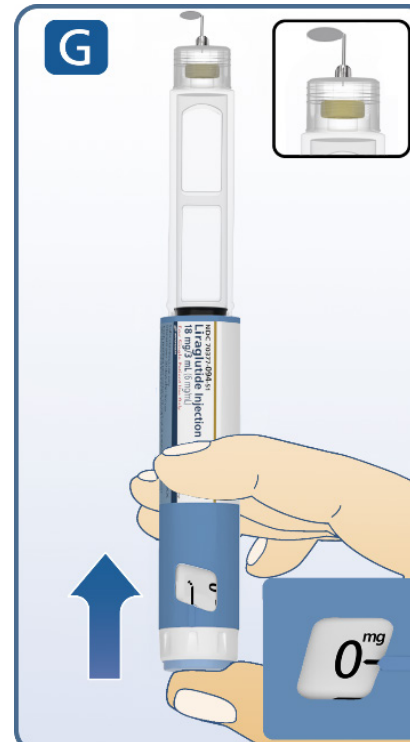


Step D. Prepare the Pen

- Hold pen with needle pointing up.
- Tap cartridge gently with your finger a few times to bring any air bubbles to the top of the cartridge (See Figure F).



- Keep needle pointing up and press dose button until the black line of 0 mg lines up with pointer (See Figure G). Repeat steps C and D, up to 6 times, until a drop of liraglutide injection appears at the needle tip.



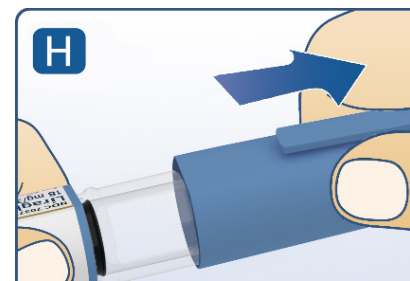
If you still see no drop of liraglutide injection, use a new pen and contact Biocon Pharma Inc. at 1-866-924-6266.

Continue to Step G under "Routine Use" →

Routine Use

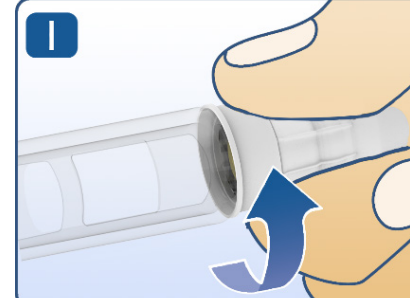
Step E. Check the Pen

- Take your liraglutide injection pen from where it is stored.
- Wash hands with soap and water before use.
- Check pen label before each use to make sure it is your liraglutide injection pen.
- Pull off pen cap (See Figure H).
- Check liraglutide injection in the cartridge. The liquid should be clear, colorless and free of particles. If not, do not use.
- Wipe the rubber stopper with an alcohol swab.

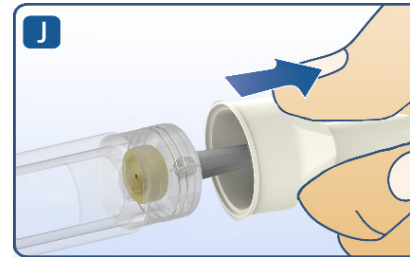


Step F. Attach the Needle

- 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).

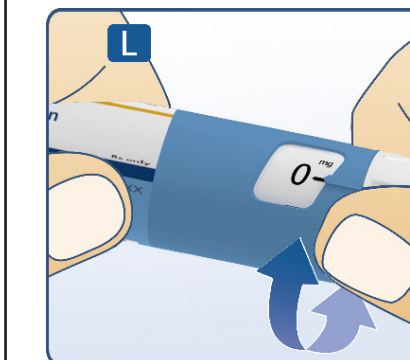


- Pull off inner needle cap and throw away (See Figure K). A small drop of liquid may appear. This is normal.



Step G. Dial the Dose

- Liraglutide injection pen can give a dose of 0.6 mg (starting dose), 1.2 mg or 1.8 mg. Be sure that you know the dose of liraglutide injection that is prescribed for you.
- Turn the dose selector until the black line of your needed dose lines up with the pointer (0.6 mg, 1.2 mg or 1.8 mg) (See Figure L).



0.6^{mg} 0.6 mg selected

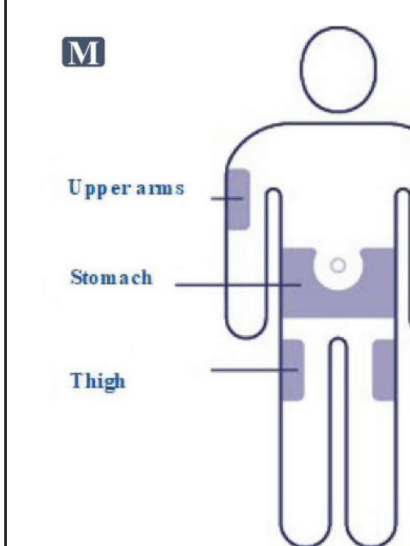
1.2^{mg} 1.2 mg selected

1.8^{mg} 1.8 mg selected

- 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, change it by turning the dose selector backwards or forwards until the black line of the correct dose lines up with the pointer. Be careful not to press the dose button when turning the dose selector. This may cause liraglutide injection to come out.

Step H. Injecting the Dose

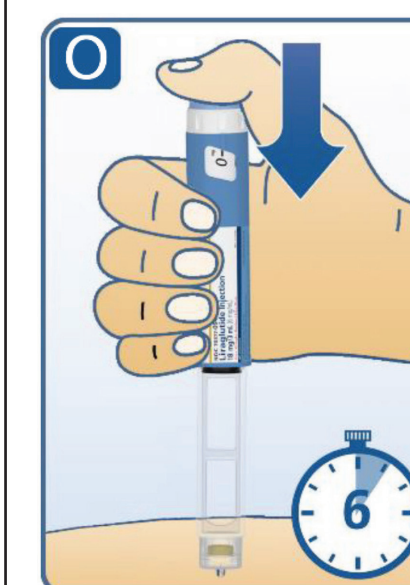
- Choose your injection site in either the stomach (abdomen), thigh, or upper arm (only if caregiver administered) and wipe the skin with an alcohol swab (See Figure M). Let the injection site dry before you inject your dose.
- Insert needle into your skin using the injection technique shown to you by your healthcare provider. **Do not inject liraglutide injection into a vein or muscle.**



- Press down on the center of the dose button to inject until the black line of 0 mg lines up with the pointer (See Figure N).
- Be careful not to touch the dose display with your other fingers. This may block the injection.

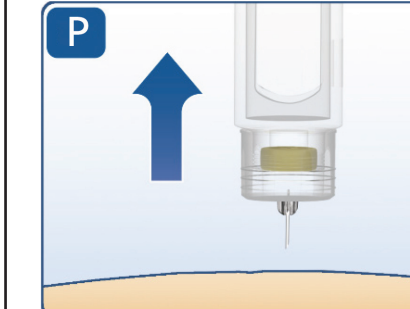


- Keep the dose button pressed down and make sure that you keep the needle under the skin for a full count of 6 seconds to make sure the full dose is injected. Keep your thumb on the injection button until you remove the needle from your skin (See Figure O).
- Change (rotate) your injection sites within the area you choose for each dose. **Do not use the same injection site for each injection.**



Step I. Withdraw Needle

- You may see a drop of liraglutide injection at the needle tip. This is normal and it does not affect the dose you just received. If blood appears after you take the needle out of your skin, apply light pressure with a cotton ball or gauze, but **do not rub the area** (See Figure P).



Step J. Remove and Dispose of the Needle

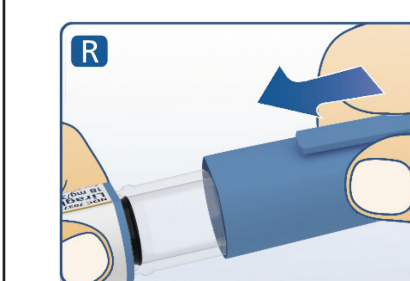
- Carefully put the outer needle cap over the needle (See Figure Q). Unscrew the needle.
- Safely remove the needle from your liraglutide injection pen after each use.
- Put your used liraglutide injection pen and needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and pens in your household trash.



- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. Do not reuse or share your needles with other people. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Caring for your liraglutide injection pen

- After removing the needle, put the pen cap on your liraglutide injection pen and store your liraglutide injection pen without the needle attached (See Figure R). It is prefilled and is disposable.
- Do not try to repair your pen or pull it apart.
- Keep your liraglutide injection pen away from dust, dirt and liquids.
- If cleaning is needed, wipe the outside of the pen with a clean, damp cloth.



How should I store liraglutide injection?

Before use:

- Store your new, unused liraglutide injection pen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If liraglutide injection is stored outside of refrigeration (by mistake) prior to first use, it should be used or thrown away within 30 days.
- Do not freeze liraglutide injection or use liraglutide injection if it has been frozen. Do not store liraglutide injection near the refrigerator cooling element.

Pen in use:

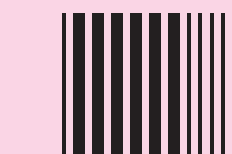
- Use a liraglutide injection pen for only 30 days. Throw away a used liraglutide injection pen 30 days after you start using it, even if some medicine is left in the pen.
- Store your liraglutide injection pen at room temperature between 59°F to 86°F (15°C to 30°C), or in a refrigerator between 36°F to 46°F (2°C to 8°C).
- When carrying the pen away from home, store the pen at room temperature between 59°F to 86°F (15°C to 30°C).
- If liraglutide injection has been exposed to temperatures above 86°F (30°C), it should be thrown away.
- Protect your liraglutide injection pen from heat and sunlight.
- Keep the pen cap on when your liraglutide injection pen is not in use.
- Always remove the needle after each injection and store your pen without the needle attached. This reduces the risk of contamination, infection, leakage and inaccurate dosing.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Revised: 03/2025

This product is subject to medical prescription only.



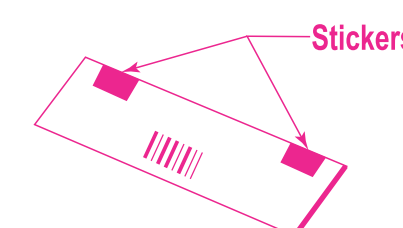
Liraglutide Injection
18mg/3 mL (6mg/mL)
(1.8mg) Prefilled Pen



BF01722/01 BPCM0378/02

Note : Booklet to be sealed with
2 numbers of transparent perforated stickers.

Size: 13x30mm plain perforated tape
Material: UPM 6L/RP37/01 PP CLEAR TC50/RP37/WG65



Pharmacode



12225

ARTWORK DETAILS

NAME OF THE PRODUCT	Liraglutide Injection 18mg/3 mL (6mg/mL) (1.8mg) Prefilled Pen	COMPONENT	IFU & Medication guide
MFG. SITE	Biocon Biologics Limited	DIMENSIONS	Open Size: 750 (w) x 440 (H) mm Folding Size: 43.30mm-9 folds, 30mm-1 fold, 20mm-1 fold x 150 (H) mm.
CUSTOMER / PARTNER	Biocon Pharma Inc.,	DESIGN / STYLE	NA
COUNTRY	USA	PANTONE COLOURS	Pantone 284 U CMYK
PACK	NA	FONTS	Helvetica Neue LT Pro
ARTWORK CODE	BPCM0378/02	MINIMUM FONT SIZE	10 Points
PHARMA CODE	12225	BAR CODE	NA
SPECIFICATIONS	60 GSM Maplitho Paper		
CHANGE CONTROL REFERENCE NO.	113063		

SPECIAL INSTRUCTIONS (IF ANY) | Note : Booklet to be sealed with 2 numbers of transparent perforated stickers. Size:13x30mm plain perforated tape Material : UPM 6L/RP37/01 PP CLEAR TC50/RP37/WG65 Warning color to be referred for the key line.

Artwork Reviewed and Approved by

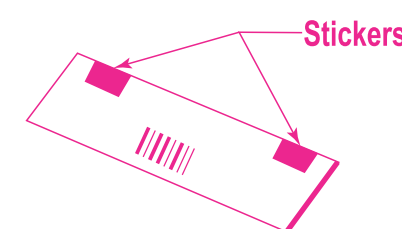
	Artwork Designed by	Packaging Development	Marketing	PV / Medical	Regulatory	QA
(Sign. & Date)						
NAME						

Medication Guide Liraglutide (lir' a gloo' tide) injection, for subcutaneous use
Read this Medication Guide before you start using liraglutide injection and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.
What is the most important information I should know about liraglutide injection? Liraglutide injection may cause serious side effects, including:
<ul style="list-style-type: none"> • Possible thyroid tumors, including cancer. Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats and mice, liraglutide injection and medicines that work like liraglutide injection caused thyroid tumors, including thyroid cancer. It is not known if liraglutide injection will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people. • Do not use liraglutide injection if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
What is liraglutide injection?
Liraglutide injection is an injectable prescription medicine used:
<ul style="list-style-type: none"> • along with diet and exercise to improve blood sugar (glucose) in adults and children who are 10 years of age and older with type 2 diabetes mellitus. • to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes mellitus with known heart disease. • Liraglutide injection is not recommended for people who take liraglutide or other medicines called glucagon-like peptide-1 (GLP-1) receptor agonists. • It is not known if liraglutide injection is safe and effective to lower blood sugar (glucose) in children under 10 years of age.
Who should not use liraglutide injection? Do not use liraglutide injection if:
<ul style="list-style-type: none"> • you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • you have had a serious allergic reaction to liraglutide or any of the ingredients in liraglutide injection. See the end of this Medication Guide for a complete list of ingredients in liraglutide injection. See "What are the possible side effects of liraglutide injection?" for symptoms of a serious allergic reaction.
What should I tell my healthcare provider before using liraglutide injection? Before using liraglutide injection, tell your healthcare provider if you have any other medical conditions, including if you:
<ul style="list-style-type: none"> • have or have had problems with your pancreas. • have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food. • are scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). • are pregnant or plan to become pregnant. It is not known if liraglutide will harm your unborn baby. Tell your healthcare provider if you become pregnant while using liraglutide injection. • are breastfeeding or plan to breastfeed. It is not known if liraglutide passes into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using liraglutide injection.
Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Liraglutide injection may affect the way some medicines work and some medicines may affect the way liraglutide injection works.
Before using liraglutide injection, talk to your healthcare provider about low blood sugar and how to manage it. Tell your healthcare provider if you are taking other medicines to treat diabetes, including insulin or sulfonylureas. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.
How should I use liraglutide injection?
<ul style="list-style-type: none"> • Read the Instructions for Use that comes with liraglutide injection. • Use liraglutide injection exactly as your healthcare provider tells you to. • Your healthcare provider should show you how to use liraglutide injection before you use it for the first time. • Inject your dose of liraglutide injection under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. Do not inject liraglutide injection into a muscle (intramuscularly) or vein (intravenously). • Use liraglutide injection 1 time each day, at any time of the day. • If you miss a dose of liraglutide injection, take the missed dose at the next scheduled dose. Do not take 2 doses of liraglutide injection at the same time. • Liraglutide injection may be taken with or without food. • Do not mix insulin and liraglutide together in the same injection. • You may give an injection of liraglutide and insulin in the same body area (such as your stomach area), but not right next to each other. • Change (rotate) your injection site with each injection. Do not use the same site for each injection. • Do not share your liraglutide injection pen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them. • If you take too much liraglutide injection, call your healthcare provider or the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away. • The liraglutide injection pen you are using should be thrown away 30 days after you start using it.

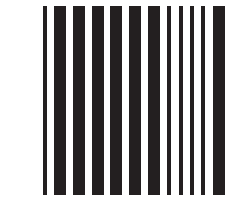
What are the possible side effects of liraglutide injection? Liraglutide injection may cause serious side effects, including:
<ul style="list-style-type: none"> • See "What is the most important information I should know about liraglutide injection?" • inflammation of your pancreas (pancreatitis). Stop using liraglutide injection and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back. • low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use liraglutide injection with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. In children who are 10 years of age and older, the risk for low blood sugar may be higher with liraglutide injection regardless of use with another medicine that can also lower blood sugar.
Signs and symptoms of low blood sugar may include:
<ul style="list-style-type: none"> o dizziness or light-headedness o sweating o confusion or drowsiness o headache o blurred vision o slurred speech o shakiness o fast heartbeat o anxiety, irritability, or mood changes o hunger o weakness o feeling jittery
<ul style="list-style-type: none"> • dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away. • severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use liraglutide injection. Tell your healthcare provider if you have stomach problems that are severe or will not go away. • serious allergic reactions. Stop using liraglutide injection and get medical help right away if you have any symptoms of a serious allergic reaction including: <ul style="list-style-type: none"> o swelling of your face, lips, tongue or throat o problems breathing or swallowing o severe rash or itching o fainting or feeling dizzy o very rapid heartbeat • gallbladder problems. Gallbladder problems have happened in some people who take liraglutide injection. Tell your healthcare provider right away if you get symptoms of gallbladder problems which may include: <ul style="list-style-type: none"> o pain in your upper stomach (abdomen) o fever o yellowing of skin or eyes (jaundice) o clay-colored stools • food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Liraglutide injection may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking liraglutide injection before you are scheduled to have surgery or other procedures.
The most common side effects of liraglutide injection may include nausea, diarrhea, vomiting, decreased appetite, indigestion and constipation. Talk to your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of liraglutide injection. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
General information about the safe and effective use of liraglutide injection. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use liraglutide injection for a condition for which it was not prescribed. Do not give liraglutide injection to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about liraglutide injection that is written for health professionals.
What are the ingredients in liraglutide injection? Active ingredient: liraglutide Inactive ingredients: sodium citrate dihydrate, propylene glycol, phenol and water for injection. Hydrochloric acid or sodium hydroxide may be added to adjust pH
Manufactured by: Biocon Biologics Limited, Bengaluru 560099, India Manufactured for: Biocon Pharma Inc., Iselin, New Jersey 08830-3009, USA
This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 09/2025

Note : Booklet to be sealed with
2 numbers of transparent perforated stickers.

Size: 13x30mm plain perforated tape
Material: UPM 6L/RP37/01 PP CLEAR TC50/RP37/WG65



Pharmacode



12225

ARTWORK DETAILS

NAME OF THE PRODUCT	Liraglutide Injection 18mg/3 mL (6mg/mL) (1.8mg) Prefilled Pen	COMPONENT	IFU & Medication guide
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CUSTOMER / PARTNER	Biocon Pharma Inc.,	DESIGN / STYLE	NA
COUNTRY	USA	PANTONE COLOURS	Pantone 284 U CMYK
PACK	NA	FONTS	Helvetica Neue LT Pro
ARTWORK CODE	BPCM0378/02	MINIMUM FONT SIZE	10 Points
PHARMA CODE	12225	BAR CODE	NA
SPECIFICATIONS	60 GSM Maplitho Paper		
CHANGE CONTROL REFERENCE NO.	113063		
SPECIAL INSTRUCTIONS (IF ANY)	Note : Booklet to be sealed with 2 numbers of transparent perforated stickers. Size:13x30mm plain perforated tape Material : UPM 6L/RP37/01 PP CLEAR TC50/RP37/WG65 Warning color to be referred for the key line.		
Artwork Reviewed and Approved by			
	Artwork Designed by	Packaging Development	Marketing
			PV / Medical
			Regulatory
			QA
(Sign. & Date)			
NAME			