

Step 1. Prepare your pen with a new needle

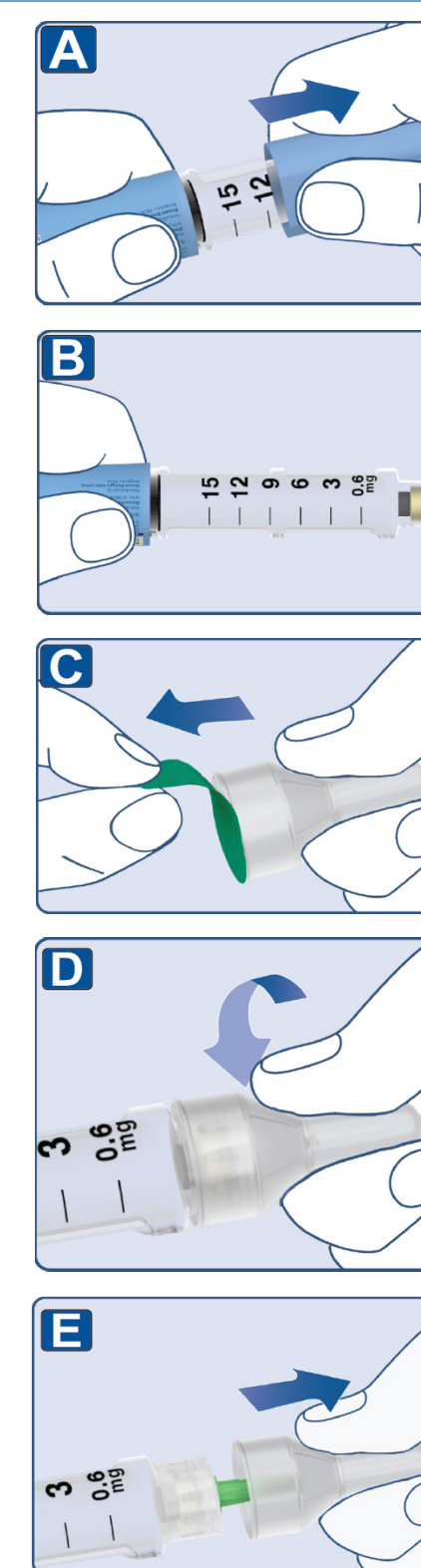
- Wash your hands with soap and water.
- Check the name and colored label of your pen, to make sure that it contains liraglutide injection. This is especially important if you take more than 1 type of medicine.
- Pull off the pen cap.

- Check that liraglutide injection in your pen is clear and colorless. Look through the pen window. If liraglutide injection looks cloudy, do not use the pen.

- Take a new needle, and tear off the paper tab.

- Push the needle straight onto the pen. Turn until it is on tight.

- Pull off the outer needle cap. Do not throw it away.



- Pull off the inner needle cap and throw it away. A drop of liraglutide injection may appear at the needle tip. This is normal, but you must still check the liraglutide injection flow, if you use a new pen for the first time.
- Always use a new needle for each injection. This will prevent contamination, infection, leakage of liraglutide injection, and blocked needles leading to the wrong dose. Never use a bent or damaged needle.
- Do not attach a new needle to your pen until you are ready to take your injection.

Step 2. Check the liraglutide flow with each new pen.

- Check the liraglutide injection flow before your first injection with each new pen. If your liraglutide injection pen is already in use, go to Step 3. "Select your dose".
- Turn the dose selector until the dose counter shows the flow check symbol (☞).

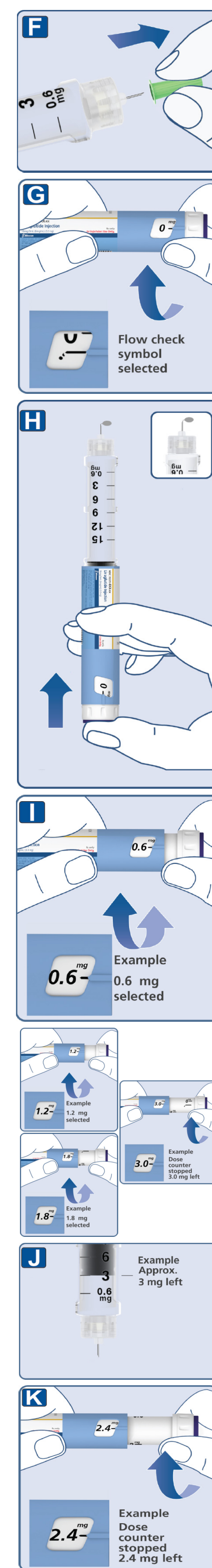
- Hold the pen with the needle pointing up. Press and push down the dose button until the dose counter shows 0. The black line indicating 0 must line up with the dose pointer.
- A drop of liraglutide injection will appear at the needle tip.
- If no drop appears, repeat Step 2 above as shown in Figures G and H up to 6 times. If there is still no drop, change the needle and repeat Step 2 as shown in Figures G and H 1 more time.
- Do not use the pen if a drop of liraglutide injection still does not appear. Contact Biocon Pharma Inc. at 1-800-824-6286.
- 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 liraglutide injection flows.
- If no drop appears, you will not inject any liraglutide injection, even though the dose counter may move. This may mean that there is a blocked or damaged needle.
- A small drop may remain at the needle tip, but it will not be injected. Only check the liraglutide injection flow before your first injection with each new pen.

Step 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 mg). Make sure you know the dose of liraglutide injection you should use. If you select the wrong dose, you can turn the dose selector forward or backwards to the correct dose.
- Always use the dose counter and the dose pointer to see how many mg you select. 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. Do not use the pen scale to set the dose. It does not show exactly how much liraglutide injection is left in your pen. Only doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg can be selected with the dose selector. The black line indicating the selected dose must line up exactly with the dose pointer to make sure that you get a correct dose.
- The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select for each dose. You can select up to 3 mg each dose. When your pen contains less than 3 mg the dose counter stops before 3 mg is shown. The dose selector clicks when turned forward, backwards or past the number of mg left. Do not count the pen clicks.

How much liraglutide injection is left?

- The pen scale shows you about how much liraglutide injection is left in your pen.
- To see how much liraglutide injection is left, use the dose counter: Turn the dose selector until the dose counter stops. If it shows 3, at least 3 mg are left in your pen. If the dose counter stops before 3 mg, there is not enough liraglutide injection left for a full dose of 3 mg.
- If you need more liraglutide injection than what is left in your pen Only if trained or told by your healthcare provider, you may split your dose between your current pen and a new pen. Use a calculator to plan the doses as instructed by your healthcare provider.
- Be very careful to calculate correctly. If you are not sure how to split your dose using 2 pens, then select and inject the dose you need with a new pen.



Step 4. Inject your dose

- Insert the needle into your skin as your healthcare provider has shown you.
- Make sure you can see the dose counter. Do not cover it with your fingers. This could stop the injection.

- Press and push down the dose button until the dose counter shows 0. The black line indicating 0 must line up with the dose pointer.

- Keep the needle in your skin after the dose counter has returned to 0 and count slowly to 6.
- If the needle is removed earlier, you may see a stream of liraglutide injection coming from the needle tip. If this happens, the full dose will not be delivered.

- Remove the needle from your skin. If blood appears at the injection site, press lightly. Do not rub the area.
- 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?
 - If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
 - If this happens you have not received any liraglutide injection even though the dose counter has moved from the original dose that you have set.
- How to handle a blocked needle? Change the needle as described in Step 5, and repeat all steps starting with Step 1: "Prepare your pen with a new needle". Make sure you select the full dose you need. Never touch the dose counter when you inject. This can stop the injection. You may see a drop of liraglutide injection at the needle tip after injecting. This is normal and does not affect your dose.

Step 5. After your injection

- Carefully remove the needle from the pen. Do not put the needle caps back on the needle, to avoid needle sticks.

- Place the needle in a sharps container right away to reduce the risk of needle sticks.

- Put the pen cap on your pen after each use to protect liraglutide injection from light.

- 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.
- Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.
- Always remove the needle from your pen. This prevents contamination, infection, leakage of liraglutide injection, and blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any liraglutide injection.

- Always dispose of the needle after each injection.
- Do not throw away in the household trash. Put the needle and any empty liraglutide injection pen or any pen still containing liraglutide in a FDA-cleared sharps disposal container right away after use.
- 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 labelled 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. 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.
- Safely dispose of liraglutide injection that is out of date or no longer needed.

Important

- Caregivers must be very careful when handling used needles to prevent needle sticks and cross infection.
- Never use a syringe to withdraw liraglutide injection from your pen.
- Always carry an extra pen and new needles with you, in case of loss or damage.
- Always keep your pen and needles out of reach of others, especially children.
- Do not share your liraglutide injection pen or needles with anyone else. You may give an infection to them or get an infection from them.
- Always keep your pen with you. Do not leave it in a car or other place where it can get too hot or too cold.

Caring for your pen

- Do not drop your pen or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the liraglutide injection flow before you inject.
- 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. If necessary, clean it with mild detergent on a moistened cloth.

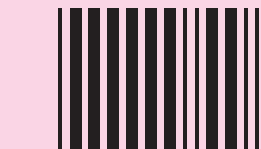
How should I store my liraglutide injection pen?

- Store your new, unused liraglutide injection pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store your pen in use for 30 days at 59°F to 86°F (15°C to 30°C) or in a refrigerator at 36°F to 46°F (2°C to 8°C).
- The liraglutide injection pen you are using should be thrown away after 30 days, even if it still has liraglutide injection left in it.
- Do not freeze liraglutide injection. Do not use liraglutide injection if it has been frozen.
- Unused liraglutide injection pens may be used until the expiration date printed on the label, if kept in the refrigerator.
- Keep liraglutide injection away from heat and out of the light. Brands listed are the trademarks of their respective owner.

This Medication Guide and Instructions for Use have been approved by the U.S. Food and Drug Administration. Revised: 04/2024

This product is subject to medical prescription only.

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

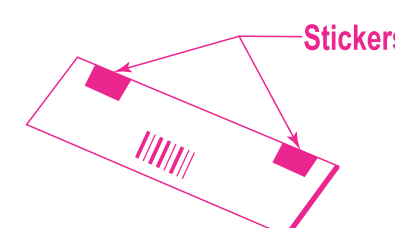


BF01729/01 BPCM0383/01



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



12235

ARTWORK DETAILS

NAME OF THE PRODUCT	Liraglutide Injection 18 mg/3 mL (6 mg/mL) 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	BPCM0383/01	MINIMUM FONT SIZE	9 Points
PHARMA CODE	12235	BAR CODE	NA
SPECIFICATIONS	60 GSM Maplitho Paper		
CHANGE CONTROL REFERENCE NO.	111883		

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						

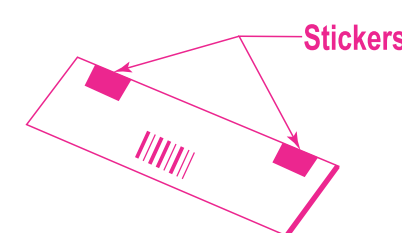
MEDICATION GUIDE	
Liraglutide (lir" a gloo" tide) injection, for subcutaneous use	
What is the most important information I should know about liraglutide injection?	
Serious side effects may happen in people who take liraglutide injection, including:	
<ul style="list-style-type: none"> Possible thyroid 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 for adults with obesity or overweight (excess weight) who also have weight related medical problems, and children aged 12 to 17 years with a body weight above 132 pounds (60 kg) and obesity to help them lose weight and keep the weight off.	
<ul style="list-style-type: none"> Liraglutide injection should be used with a reduced calorie diet and increased physical activity. Liraglutide injection is not recommended for people who also 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 in children under 12 years of age. It is not known if liraglutide injection is safe and effective in children aged 12 to 17 years with type 2 diabetes. 	
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. 	
Before taking liraglutide injection, tell your healthcare provider about all of your 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). have or have had depression or suicidal thoughts, or mental health issues. are breastfeeding or plan to breastfeed. It is not known if liraglutide passes into your breast milk. You and your healthcare provider should decide if you will use liraglutide injection or breastfeed. 	
Tell your healthcare provider about all the medicines you take including prescription, over-the-counter medicines, vitamins, and herbal supplements. Liraglutide injection may affect the way some medicines work and some other medicines may affect the way liraglutide injection works.	
Tell your healthcare provider if you take diabetes medicines, especially insulin and sulfonylurea medicines. Talk with your healthcare provider if you are not sure if you take any of these medicines. 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. Use liraglutide injection with a reduced-calorie diet and increased physical activity. Liraglutide injection is injected under the skin (subcutaneously) in your stomach area (abdomen), upper leg (thigh), or upper arm. Do not inject into a muscle (intramuscularly) or vein (intravenously). Liraglutide injection is injected 1 time each day, at any time during the day. Start liraglutide injection with 0.6 mg per day in your first week. In your second week, increase your daily dose to 1.2 mg. In the third week, increase your daily dose to 1.8 mg. In the fourth week, increase your daily dose to 2.4 mg and in the fifth week onwards, increase your daily dose to the full dose of 3 mg. After that, do not change your dose unless your healthcare provider tells you to. Children may reduce their dose to 2.4 mg daily if the maximum dose is not tolerated. If you miss your daily dose of liraglutide injection, just take your next daily dose as usual on the following day. Do not take an extra dose of liraglutide injection or increase your dose on the following day to make up for your missed dose. If you miss your dose of liraglutide injection for 3 days or more, call your healthcare provider to talk about how to restart your treatment. Liraglutide injection may be taken with or without food. 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 Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away. Throw away the used liraglutide injection pen after 30 days. 	

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 the 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 stomach area (abdomen) to your back. increased risk of low blood sugar (hypoglycemia) in adults with type 2 diabetes, especially those who also take medicines to treat type 2 diabetes mellitus such as an insulin or a sulfonylurea and in children who are 12 years of age and older without type 2 diabetes mellitus. Low blood sugar in patients with adults with type 2 diabetes and in children without type 2 diabetes mellitus who receive liraglutide injection can be both a serious and common side effect. Talk to your healthcare provider about how to recognize and treat low blood sugar. You should check your blood sugar before you start taking liraglutide injection and while you take liraglutide injection.
Signs and symptoms of low blood sugar may include:
<ul style="list-style-type: none"> dizziness or light-headedness sweating confusion or drowsiness headache blurred vision slurred speech shakiness fast heartbeat anxiety, irritability, or mood changes hunger weakness feeling jittery
Talk to your healthcare provider about how to recognize and treat low blood sugar. You should check your blood sugar before you start taking liraglutide injection and while you take liraglutide injection.
<ul style="list-style-type: none"> increased heart rate. Liraglutide injection can increase your heart rate while you are at rest. Your healthcare provider should check your heart rate while you take liraglutide injection. Tell your healthcare provider if you feel your heart racing or pounding in your chest and it lasts for several minutes. 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"> swelling of your face, lips, tongue, or throat problems breathing or swallowing severe rash or itching fainting or feeling dizzy very rapid heartbeat gallbladder problems. Liraglutide injection may cause gallbladder problems including gallstones. Some gallbladder problems need surgery. Call your healthcare provider if you have any of the following symptoms: <ul style="list-style-type: none"> pain in your upper stomach (abdomen) fever yellowing of your skin or eyes (jaundice) clay-colored stools depression or thoughts of suicide. You should pay attention to any mental changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you. 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 in adults include:
<ul style="list-style-type: none"> nausea diarrhea constipation vomiting injection site reaction low blood sugar (hypoglycemia) headache upset stomach (dyspepsia) tiredness (fatigue) dizziness stomach pain change in enzyme (lipase) levels in your blood
Additional common side effects in children are fever and gastroenteritis
Talk to your healthcare provider if you have any side effect that bothers you or that 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.
Keep your liraglutide injection pen, pen needles, and all medicines out of the reach of children.

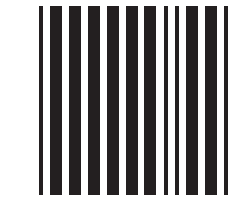
General information about the safe and effective use of liraglutide injection.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use liraglutide injection for a condition for which it was not prescribed. Do not give liraglutide injection to other people, even if they have the same symptoms that you have. It may harm them.
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 the pH.
Manufactured by: Biocon Biologics Limited, Bengaluru 560099, India.
Manufactured for: Biocon Pharma Inc., Iselin, New Jersey 08830-3009, USA
Brands listed are the trademarks of their respective owner.
This Medication Guide has been approved by the U.S. Food and Drug Administration.
Revised: 07/2025

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



12235

ARTWORK DETAILS

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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	BPCM0383/01	MINIMUM FONT SIZE	9 Points
PHARMA CODE	12235	BAR CODE	NA
SPECIFICATIONS	60 GSM Maplitho Paper		
CHANGE CONTROL REFERENCE NO.	111883		

SPECIAL INSTRUCTIONS (IF ANY) | Note : Booklet to be sealed with 2 numbers of transparent perforated stickers. Size:13x30mm plain perforated tape
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Artwork Reviewed and Approved by

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