

For Adults and Pediatric Patients Aged 12 Years and Older...

Teva's Liraglutide Injection Dosage Escalation Schedule

The daily dosage escalation schedule for Teva's Liraglutide Injection was designed to help patients get used to their medication while reducing the risk of gastrointestinal side effects. Below is the dosage escalation schedule to help you keep track throughout your journey.

START		INCREASE EACH WEEK		STAY
WEEK 1 DAILY DOSE	WEEK 2 DAILY DOSE	WEEK 3 DAILY DOSE	WEEK 4 DAILY DOSE	WEEK 5 DAILY DOSE
0.6 mg (starting dose)	1.2 mg	1.8 mg	2.4 mg	3 mg (full dose)

Teva's Liraglutide Injection should be taken as prescribed by your healthcare provider.

Call your healthcare provider if an increase during the dose escalation period or the 3 mg dose cannot be tolerated.

Do not change your dose unless advised by your healthcare provider.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about liraglutide injection?

Serious side effects may happen in people who take liraglutide injection, including: 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).

Please see the full [Prescribing Information](#), including [Boxed Warning and Medication Guide](#), and [Important Safety Information](#) throughout.

IMPORTANT SAFETY INFORMATION (CON'T.)

Who should not take liraglutide injection?

Do not receive 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).
- you have had a serious allergic reaction to liraglutide or any of the 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:

- 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 and 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 to show your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of liraglutide injection?

Liraglutide Injection may cause serious side effects, including:

- **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 sulfonylureas 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.

Please see the full [Prescribing Information](#), including [Boxed Warning and Medication Guide](#), and [Important Safety Information](#) throughout.



IMPORTANT SAFETY INFORMATION (CON'T.)

- Signs and symptoms of low blood sugar may include:
 - 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.

- **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:
 - 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:
 - pain in your upper stomach (abdomen)
 - fever
 - yellowing of your skin or eyes (jaundice)
 - clay-colored stools

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IMPORTANT SAFETY INFORMATION (CON'T.)

- **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:

- 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.

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.

- 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.

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