Zeptide

(Tirzepatide)

Solution for Injection
Multi Dose Pre-Filled Pen for Subcutaneous Use Only

زیپٹائڈ

(ٹرزیپیٹائڈ) انجیکشن
پری فلڈ پین

2.5mg **5mg** **7.5mg** **10mg** **12.5mg** **15mg**

Composition:
Zeptide 2.5mg Multi Dose Pre-filled Pen:
Each Pre-filled Pen of 2.4mL contains:
Tirzepatide ..... 10 mg
Each dose contains 2.5mg of Tirzepatide in 0.6mL solution.
Zeptide 5mg Multi Dose Pre-filled Pen:
Each Pre-filled Pen of 2.4mL contains:
Tirzepatide ..... 20 mg
Each dose contains 5mg of Tirzepatide in 0.6mL solution.
Zeptide 7.5mg Multi Dose Pre-filled Pen:
Each Pre-filled Pen of 2.4mL contains:
Tirzepatide ..... 30 mg
Each dose contains 7.5mg of Tirzepatide in 0.6mL solution.
Zeptide 10mg Multi Dose Pre-filled Pen:
Each Pre-filled Pen of 2.4mL contains:
Tirzepatide ..... 40 mg
Each dose contains 10mg of Tirzepatide in 0.6mL solution.
Zeptide 12.5mg Multi Dose Pre-filled Pen:
Each Pre-filled Pen of 2.4mL contains:
Tirzepatide ..... 50 mg
Each dose contains 12.5mg of Tirzepatide in 0.6mL solution.
Zeptide 15mg Multi Dose Pre-filled Pen:
Each Pre-filled Pen of 2.4mL contains:
Tirzepatide ..... 60 mg
Each dose contains 15mg of Tirzepatide in 0.6mL solution.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor , pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zeptide is and what it is used for.
2. What you need to know before you use Zeptide.
3. How to use Zeptide.
4. Possible side effects.
5. Storage and Instructions
6. Other information.

1. WHAT ZEPTIDE IS AND WHAT IT IS USED FOR

Zeptide contains the active substance tirzepatide. It belongs to a group of medicines that act on two gut-hormone receptors, GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1), known as dual GIP/GLP-1 receptor agonists.

Zeptide is used in adults for:

Type 2 diabetes mellitus — to lower blood sugar levels, only when these are high. It is used on its own, when metformin cannot be taken, or together with other diabetes medicines (taken by mouth and/or insulin given by injection) when these are not enough on their own to control blood sugar. You should continue to follow the diet and exercise advice given by your doctor, pharmacist or health care provider.

Weight management — together with a reduced-calorie diet and increased physical activity for weight loss and weight maintenance in adults who have a Body Mass Index (BMI) of 30 kg/m² or more (obesity), or a BMI of at least 27 kg/m² but less than 30 kg/m² (overweight) together with at least one weight-related health problem (such as high blood pressure, prediabetes, type 2 diabetes, abnormal blood fat levels, obstructive sleep apnoea, or a history of heart attack, stroke or other blood vessel disease). Zeptide primarily works by regulating your appetite, helping you feel fuller and less hungry, so that you eat less and reduce your body weight. Zeptide is supplied as a multidose pre-filled pen. Each pen contains 4 fixed once-weekly doses. It is available in six pen strengths, which differ only in the amount of tirzepatide delivered per weekly dose:

Pen	Dose delivered per weekly injection (0.6 mL)
Zeptide 10 mg	2.5 mg
Zeptide 20 mg	5 mg
Zeptide 30 mg	7.5 mg
Zeptide 40 mg	10 mg
Zeptide 50 mg	12.5 mg
Zeptide 60 mg	15 mg

Your doctor has chosen the pen strength that is right for you. Do not use a pen other than the one your doctor has prescribed.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ZEPTIDE

Do not use Zeptide if you are hypersensitive (allergic) to tirzepatide or any of the other ingredients of Zeptide (listed in section 6).

2.1 Do not use Zeptide
- If you are allergic (hypersensitive) to tirzepatide or any of the other ingredients of this medicine (listed in section 6).
- If you, or any member of your family, have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- If you have an inherited condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

If any of the above applies to you, or you are in doubt, do not use Zeptide and talk to your doctor before using this medicine.

2.2 Warnings and Precautions

Talk to your doctor, pharmacist or health care provider before using Zeptide:
- **If you or a family member have ever had thyroid cancer, or a lump or swelling in the neck**: In animal studies, tirzepatide caused thyroid tumours. It is not known whether Zeptide causes thyroid tumours, including medullary thyroid carcinoma, in humans. Tell your doctor straight away if you notice a lump or swelling in the neck, difficulty swallowing, hoarseness that does not go away, or shortness of breath.
- **If you have, or have ever had, pancreatitis** (inflammation of the pancreas, which may cause severe, continuous pain in the stomach and back). Stop using Zeptide and contact your doctor straight away if you get severe stomach pain that does not go away.
- **If you have severe problems with food digestion or stomach emptying** (including severe gastroparesis), as Zeptide slows the movement of food through your stomach.
- **If you have a problem with your eyes caused by diabetes** (diabetic retinopathy) or swelling at the back of the eye (macular oedema), since rapid improvement in blood sugar control can temporarily worsen these conditions.
- **If you are using a sulphonylurea** (another diabetes medicine) or insulin, as low blood sugar (hypoglycaemia) can occur. Your doctor may need to lower the dose of these other medicines.
- **If you have, or have had, problems with your gallbladder** (such as gallstones).
- **If you have severe kidney or liver problems.**
- **If you experience vomiting, nausea and/or diarrhoea after starting Zeptide,** as this may cause loss of fluids (dehydration), which can affect your kidney function. It is important to drink plenty of fluids to avoid dehydration. Contact your doctor if you have any questions or concerns.

Children and adolescents. Zeptide should not be given to children and adolescents below 18 years of age, as it has not been studied in this age group.

2.3 Other medicines and Zeptide

Always tell your doctor, pharmacist or health care provider if you are taking, have recently taken, or might take any other medicine. This includes all complementary or alternative medicines.

In particular, tell your doctor if you are using:
- a sulphonylurea or insulin — the risk of low blood sugar (hypoglycaemia) is increased, and your doctor may need to lower the dose of these medicines;
- any other GLP-1 receptor agonist medicine (for example semaglutide, liraglutide, dulaglutide, exenatide) or any other tirzepatide-containing product — Zeptide should not be used together with these;
- warfarin or other blood-thinning (anticoagulant) medicines — your doctor may need to monitor your blood clotting more closely after you start Zeptide, because it can slow stomach emptying and change how quickly some oral medicines are absorbed;
- an oral contraceptive (the pill) — see section 2.5 below;
- any other medicine taken by mouth, since the effect of Zeptide on stomach emptying may change how quickly these medicines are absorbed.

2.4 Zeptide with food and drink

Zeptide can be used at any time of the day, with or without food. There are no specific restrictions on food or drink while using Zeptide. See section 3 for how and when to use your injection.

2.5 Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, 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 this medicine.

Do not use Zeptide if you are pregnant, as the effects of this medicine on an unborn child are not known. It is recommended that you use contraception while using Zeptide and for a period after you stop, as advised by your doctor.

If you have obesity or are overweight and use oral contraceptives, you should also use a barrier method of contraception (such as a condom), or switch to a non-oral method of contraception, for 4 weeks after starting Zeptide and for 4 weeks after each dose increase, because the absorption of your oral contraceptive may be reduced during this time.

It is not known whether tirzepatide passes into breast milk. A risk to the newborn/infant cannot be excluded. Talk to your doctor before using Zeptide if you are breast-feeding or planning to breast-feed. You and your doctor should decide whether you should stop breast-feeding or stop using Zeptide.

There are no specific human fertility data for tirzepatide. Discuss with your doctor if you are planning a pregnancy.

2.6 Driving and using machines

It is not always possible to predict to what extent Zeptide may interfere with your daily activities. Zeptide is unlikely, on its own, to affect your ability to drive or use machines. However, if you use Zeptide together with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur, which can reduce your ability to concentrate. Patients should ensure that they do not drive or use machines until they are aware of the extent to which Zeptide affects them, and should avoid these activities if they notice signs of low blood sugar, such as headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating.

3. HOW TO USE ZEPTIDE

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

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

3.1 Dosage

The usual starting dose is Zeptide 10 mg (2.5 mg per injection), once weekly, for 4 weeks. This starting dose is for treatment initiation and is not an effective dose for blood sugar or weight control.

After 4 weeks, your doctor will usually increase your dose to Zeptide 20 mg (5 mg per injection), once weekly. If needed, your doctor may further increase your dose, in steps of one pen strength, to Zeptide 30 mg, 40 mg, 50 mg and then 60 mg, always leaving a gap of at least 4 weeks between dose increases so that your body can adjust. The maximum weekly dose is Zeptide 60 mg (15 mg per injection).

Treatment step	Pen used	Dose injected once weekly
Weeks 1–4 (starting dose)	Zeptide 10 mg	2.5 mg
Weeks 5–8 (or as advised)	Zeptide 20 mg	5 mg
If needed	Zeptide 30 mg	7.5 mg
If needed	Zeptide 40 mg	10 mg
If needed	Zeptide 50 mg	12.5 mg
If needed (maximum dose)	Zeptide 60 mg	15 mg

Do not change your dose, or the pen strength you use, unless your doctor has told you to.
Your doctor will tell you how long your treatment with Zeptide will last. Do not stop treatment early. If you have the impression that the effect of Zeptide is too strong or too weak, tell your doctor or pharmacist.
If you use Zeptide together with a sulphonylurea or insulin, it is important that you test your blood glucose as instructed by your doctor, pharmacist or health care provider.

3.2 Administration
Zeptide is injected under the skin (subcutaneously). You will be shown how to inject yourself by your doctor, pharmacist or nurse before you use Zeptide for the first time. Follow these steps each time you inject:
1. Wash your hands with soap and water.
2. Remove the pen from the refrigerator (or room-temperature storage, if already in use) and pull the pen cap straight off. Check the pen label matches your prescribed dose and that the expiry date has not passed. Do not use the pen if it looks damaged, or if the medicine is cloudy, discoloured, or contains particles. Zeptide should be clear and colourless to slightly yellow.
3. Wipe the rubber seal of the pen with an alcohol swab.
4. Attach a new pen needle by pushing it straight onto the pen and twisting until tight. Always use a new needle for each injection.
5. Prime the pen before the first injection from a new pen, following the device priming steps, until a drop of medicine appears at the needle tip. Do not inject this primed amount into your body.
6. Choose an injection site: the stomach area (abdomen, at least 5 cm from the belly button), the front of the thigh, or (with the help of another person) the back of the upper arm. Use a different exact spot each week, even if you use the same general body area (rotate sites). If you also inject insulin, use a different injection site for that injection.
7. Turn the dose knob until the dose window shows a full dose, insert the needle into your skin, then press the dose knob fully in and hold it for a slow count of 5, until "0" appears in the dose window, before removing the needle.
8. If you see a drop of blood after removing the needle, press gently on the site with gauze or a cotton ball. Do not rub the site.
9. Carefully remove and discard the needle into a sharp disposal container, and replace the pen cap.

Zeptide is taken once weekly. You can inject it at any time of day, with or without food. Try to use it on the same day each week. If necessary, you may change your weekly injection day, as long as at least 3 days (72 hours) have passed since your last dose.
A complete, illustrated step-by-step guide to using the Zeptide pen is provided in the separate "Instructions for Use" leaflet included in this pack. Please read it carefully before your first injection and each time you receive a new pen.

3.3 If you use more Zeptide than you should
If you use more Zeptide than you should, talk to your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison centre. Taking too much Zeptide may cause low blood sugar, or severe nausea or vomiting.

3.4 If you forget to use Zeptide
Do not use a double dose to make up for a missed dose.
- If it has been 4 days (96 hours) or less since your missed dose, inject it as soon as you remember, then continue with your next dose on your normal scheduled day.
- If it has been more than 4 days, skip the missed dose completely and inject your next dose on your normal scheduled day.

The minimum time between two doses must always be at least 3 days.

3.5 If you stop using Zeptide
Do not stop using Zeptide without talking to your doctor first. If you have type 2 diabetes and stop using Zeptide, your blood sugar levels are likely to rise again. If you are using Zeptide for weight management and stop, you may regain some or all of the weight you have lost.

4. POSSIBLE SIDE EFFECTS
Zeptide can have side effects, although not everybody gets them. Not all side effects reported for Zeptide are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using Zeptide, please consult your health care provider for advice.
If any of the following happens, stop using Zeptide and tell your doctor immediately, or go to the casualty department at your nearest hospital:
- a lump or swelling in the neck, difficulty swallowing, hoarseness that does not go away, or shortness of breath — these may be symptoms of a thyroid problem;
- severe, continuous pain in the stomach and back, with or without vomiting — this may be a sign of inflammation of the pancreas (pancreatitis);
- swelling of the face, lips, tongue or throat, difficulty breathing or swallowing, a fast heartbeat, or severe itching of the skin with raised lumps — these may be signs of a serious allergic reaction.

These are all serious side effects. You may need urgent medical attention or hospitalisation.

4.1 Frequent side effects
Tell your doctor if you notice any of the following:
- Feeling sick (nausea) and diarrhoea — usually not severe; most common when starting treatment or after a dose increase, and tend to decrease over time.
- Being sick (vomiting) and constipation.
- Low blood sugar (hypoglycaemia), particularly when Zeptide is used for type 2 diabetes together with a sulphonylurea and/or insulin. Symptoms include headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating. Your doctor will tell you how to treat low blood sugar.
- Allergic reaction (hypersensitivity), such as rash, itching or eczema.
- Dizziness and, in people using Zeptide for weight management, low blood pressure.
- Decreased appetite.
- Stomach (abdominal) pain, indigestion, bloating, burping, wind (flatulence), and heartburn/acid reflux.
- Hair loss (reported in people using Zeptide for weight management).
- Feeling tired (fatigue).
- Injection site reactions (such as itching or redness).
- Fast heartbeat.
- Increased levels of pancreatic enzymes (lipase and amylase) found on blood tests.

4.2 Less frequent side effects
Tell your doctor if you notice any of the following:
- Gallstones and inflammation of the gallbladder (cholecystitis).
- Unintended weight loss (reported in people using Zeptide for type 2 diabetes).
- Pain at the injection site.
- Increased calcitonin levels in the blood.
- Change in sense of taste.
- Inflammation of the pancreas (acute pancreatitis) — see "stop using Zeptide" above.
- Severe allergic reactions (such as anaphylaxis or angioedema) — see "stop using Zeptide" above.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

4.3 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. You can also report side effects directly via https://bfbio.com/drug-safety/
By reporting side effects, you can help provide more information on the safety of this medicine.

5. STORAGE AND INSTRUCTIONS
- Store in a refrigerator at 2°C to 8°C and do not freeze.
- Can be stored unrefrigerated not above 30°C for up to 30 days.
- Protect from sunlight and heat.
- Do not use the pen if it appears damaged, discoloured and contains particulate matter.
- Keep out of the reach of children.
- For use by one person only.
- Always use a new needle for each injection.
- Keep the pen covered with cap when not in use.
- Do not store the pen with needle attached.
- Always remove and safely discard the needle after each injection.
- To be sold on the prescription of a registered medical practitioner only.

6.OTHER INFORMATION
6.1 What Zeptide contains
The active substance is tirzepatide. Each Zeptide multidose prefilled pen contains 2.4 mL of solution, providing 4 fixed once-weekly doses of 0.6 mL each, as follows:

Pen	Total tirzepatide content	Dose per 0.6 mL injection
Zeptide 10 mg	10 mg / 2.4 mL	2.5 mg
Zeptide 20 mg	20 mg / 2.4 mL	5 mg
Zeptide 30 mg	30 mg / 2.4 mL	7.5 mg
Zeptide 40 mg	40 mg / 2.4 mL	10 mg
Zeptide 50 mg	50 mg / 2.4 mL	12.5 mg
Zeptide 60 mg	60 mg / 2.4 mL	15 mg

The other ingredients are Sodium chloride, Disodium hydrogen phosphate heptahydrate, glycerol, benzyl alcohol, phenol, hydrochloric acid, sodium hydroxide and water for injection.

6.2 What Zeptide looks like
Zeptide is a clear, colourless to slightly yellow solution for injection in a multidose prefilled pen. Each prefilled pen contains 4 doses of 0.6ml which can be administered.

Please read the contents cautiously before use.
This package insert is regularly and timely updated.

Manufactured by:
BF BIOSCIENCES
BF BIOSCIENCES LIMITED
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