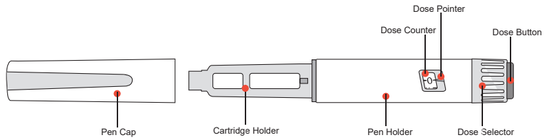
ONCE A WEEK

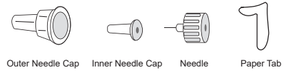
TIRZEE 4 (TIRZEPATIDE) DOSES

Instruction Manual

Read these Instructions for use before you start injecting Tirzee Multidose Prefilled Pen

Multidose Prefilled Pen for Subcutaneous and Single Patient Use Only
Each pen contains 4 doses, one dose taken weekly





ہدایت نامہ

ٹرزی ملٹی ڈوز پری فلڈ پین کے استعمال سے قبل یہ ہدایات پڑھیں۔

ٹرزی 4 ڈوزز

General Instructions:

- Wash your hands with soap and water.
- Check the name, expiry and label on your pen to make sure that it contains prescribed dose of Tirzee Multidose Prefilled Pen. Ensure the pen is not damaged.

عام ہدایات:

- اپنے ہاتھ صابن اور پانی سے دھو لیں۔
- اپنے پین کا نام، معیاد اور لیبل چیک کریں تاکہ ٹرزی ملٹی ڈوز پری فلڈ پین کی مطلوبہ خوراک کی تصدیق ہو جائے۔ اس بات کو یقینی بنائیں کہ پین خراب نہ ہو۔

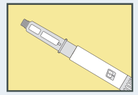
Step 1. Checking the Tirzee Multidose Prefilled Pen

پہلا مرحلہ: ٹرزی ملٹی ڈوز پری فلڈ پین کی جانچ



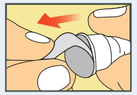
Pull off the pen cap.

پین کے ڈھکن کو ہٹا دیں۔



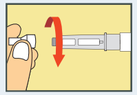
Make sure that the medicine in the pen is colorless to slightly yellow. If Tirzee Solution for Injection looks cloudy or contains particles, do not use the pen.

اس بات کو یقینی بنائیں کہ پین میں دوا رنگ کا یا ہلکی پیلی ہے۔ اگر ٹرزی سلوشن فار انجکشن کو دیکھ کر اس میں ذرات موجود ہوں تو پین کو استعمال نہ کریں۔



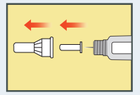
Take a new needle, and tear off the paper tab.

نئی سوئی لیں اور کاغذ کو ہٹا دیں۔



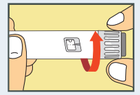
Keep the needle straight and screw it onto the pen until fixed. Do not over tighten.

سوئی کو سیدھا رکھیں اور اسے ٹھیک سے پین پر لگائیں۔ زیادہ مضبوطی سے بند نہ کریں۔



Pull off the outer needle cap and keep it for later use. Pull off the inner needle cap and discard it.

سوئی کے بیرونی ڈھکن کو ہٹا دیں اور اسے بعد میں استعمال کے لئے رکھ لیں۔ سوئی کے اندرونی ڈھکن کو ہٹا دیں اور اسے ضائع کر دیں۔





First Time Use for Each New Pen: Check the Tirzee Multidose Prefilled Pen flow

a) Turn the dose selector to the priming mark (-) until you hear 2 clicks and the priming mark aligns with the dose pointer.
b) Hold the pen with the needle pointing up.
c) Tap the cartridge holder gently to collect the air bubble at the top.
d) Keep the needle pointing upwards and press and hold the dose button until the dose counter shows "0". A drop of Tirzee Solution for Injection will appear at the needle tip.
e) If no drop appears, repeat Steps a, b, c & d up to 6 times. If there is still no drop, change the needle and repeat Steps a, b, c & d, 1 more time.
f) Do not use the pen if the drop of Tirzee Solution for Injection still does not appear.

ہر نئے پین کے استعمال سے قبل ٹرزی ملٹی ڈوز پین کا بہاؤ چیک کریں

a- ڈوز سلیکٹر کو پرائمنگ مارک (-) تک گھمائیں یہاں تک کہ دو بار کلک کی آواز سنائی دے اور پرائمنگ مارک ڈوز پوائنٹر کے ساتھ سیدھ میں آ جائے۔

b- سوئی کا رخ اوپر کی طرف رکھتے ہوئے پین کو پکڑیں۔

c- کارٹرج ہولڈر کو آہستہ سے تھپتھپائیں تاکہ ہوا کا بلبلہ اوپر کی طرف جمع ہو جائے۔

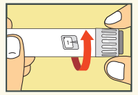
d- سوئی کا رخ اوپر کی طرف رکھتے ہوئے ڈوز بٹن کو دبائیں یہاں تک کہ ڈوز کاؤنٹر "0" دکھائے۔ ٹرزی سلوشن فار انجکشن کا ایک قطرہ سوئی کی نوک پر نظر آئے گا۔

e- اگر کوئی قطرہ نظر نہ آئے تو مرحلہ a,b,c,d کو مزید 5 بار تک دہرائیں۔ اگر پھر بھی کوئی قطرہ نظر نہ آئے تو سوئی تبدیل کریں اور مرحلہ a,b,c,d کو ایک بار مزید دہرائیں۔

f- اگر اب بھی ٹرزی سلوشن فار انجکشن کا قطرہ نظر نہ آئے تو پین استعمال نہ کریں۔

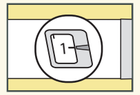
Step 2. Select the Dose

دوسرا مرحلہ: خوراک کا انتخاب



Select the dose by turning the dose selector until it stops and "1" lines up with the dose pointer.

خوراک کے لیے ڈوز سلیکٹر کو اس وقت تک گھمائیں جب تک "1" ڈوز پوائنٹر کے سیدھ میں نہ آ جائے۔

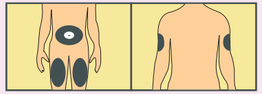


The 1 icon is equal to a full dose (0.6mL).

یہ آئیکن 1 ایک مکمل خوراک (0.6 ملی لیٹر) کے برابر ہے۔

Step 3. Inject your Dose

تیسرا مرحلہ: انجکشن لگانے کا طریقہ



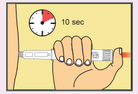
Choose your injection site. Tirzee Solution for Injection can be injected under the skin (subcutaneously) of your stomach area (abdomen) or thighs, and with the help of someone else, in the back of the upper arm.

انجکشن لگانے کی جگہ کا انتخاب کریں۔ ٹرزی سلوشن فار انجکشن کو پیٹ کے نچلے حصے (ابدومن) یا کسی اور کی مدد سے بازو کے پچھلے حصہ میں جلد کے نیچے لگایا جا سکتا ہے۔



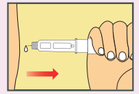
Insert the needle into the skin (make sure you can see the dose counter).

سوئی کو جلد میں داخل کریں اور اس بات کو یقینی بنائیں کہ آپ ڈوز کاؤنٹر کو دیکھ سکتے ہیں۔



Press and hold down the dose button and inject slowly until the dose counter returns to "0". Keep pressing the dose button with the needle in your skin for at least 10 seconds.

انجکشن لگانے کے لئے ڈوز بٹن کو مکمل طور پر دبائیں جب تک ڈوز کاؤنٹر واپس "0" پر نہ آ جائے۔ سوئی کو اپنی جلد میں رکھتے ہوئے ڈوز بٹن کو کم از کم ۱۰ سیکنڈ تک دبائے رکھیں۔

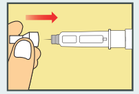


The selected Tirzee dose has been delivered. Withdraw the needle. After you have withdrawn the needle, a few droplets of Tirzee Solution for Injection may appear at the needle tip. This is normal and has no effect on the dose delivered.

ٹرزی کی منتخب خوراک آپ کے جسم میں داخل کی جا چکی ہے۔ سوئی کو اپنی جلد میں سے باہر نکالیں۔ سوئی نکالنے کے بعد ٹرزی سلوشن فار انجکشن کے چند قطرے سوئی کی نوک پر نظر آ سکتے ہیں۔ یہ عام بات ہے اس سے متم میں مختلف دوائی ٹرزی کی خوراک میں کوئی رکاوٹ پیدا نہیں ہوتی۔

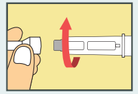
Step 4. Replacing used Needle

چوتھا مرحلہ: استعمال شدہ سوئی کو تبدیل کرنا



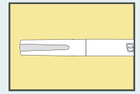
Carefully place the outer needle cap onto the needle.

سوئی کے بیرونی ڈھکن کو احتیاط سے دوائی سوئی پر لگا دیں۔



Hold the pen holder and unscrew the needle. Dispose off the needle properly as instructed by your healthcare professional.

پین ہولڈر کو پکڑیں اور سوئی کو گھما کر ہٹا دیں۔ اپنے معالج کی ہدایت کے مطابق سوئی کو درست طریقے سے ضائع کر دیں۔



Always firmly replace the pen cap after use. When the pen is empty, dispose off the pen without a needle as instructed by your healthcare professional.

استعمال کے بعد پین کے ڈھکن کو مضبوطی اور اچھی طرح لگائیں۔ جب پین خالی ہو جائے تو پین کو سوئی کے بغیر اپنے معالج کی ہدایت کے مطابق ضائع کر دیں۔

Getz pharma

Important Instructions

استعمال کے لئے اہم ہدایات

- Change (rotate) your injection site within the area you choose for each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
- Do not inject where the skin has pits, is thickened, or has lumps.
- Do not inject where the skin is tender, bruised, scaly or hard, or on scars or damaged skin.
- If you see blood after you take the needle out of your skin, press the injection site lightly. Do not rub the area.
- Do not share your needle or your pen with other people. Do not reuse needle. Never use a bent or damaged needle.
- Do not freeze Tirzee Solution for Injection. Do not use if it has been frozen.
- Store unused pen in refrigerator at 2°C - 8°C. If stored at room temperature (up to 30°C), discard unopened pen after 30 days.
- Protect from heat & light. Store pen in the original carton to protect from light.
- Used pen may be stored in refrigerator at 2°C - 8°C or at room temperature (up to 30°C). Discard the pen you are using after 30 days.
- **If you drop the Tirzee Multidose Prefilled Pen on a hard surface, do not use it.**
- Always use a new needle for each dose, to ensure sterility and prevent blocked needles. Do not store the pen with the needle attached.
- After you have taken the 4th dose (a month's treatment), you will see leftover medicine in the pen. This is normal. The leftover medicine ensures that the pen works correctly.
- Even though the pen still has medicine in it, do not use it. The pen will prevent you from dialing a full dose after you have given yourself the 4th dose. You will not be able to turn the knob after you have given yourself the 4th dose.

- اپنے انجکشن کی جگہ کو ہر بار تبدیل کریں تاکہ انجکشن کی جگہوں پر جلد میں گڑھے، گاڑھی یا جلد موٹی ہونے کے خطرہ کو کم کیا جا سکے۔
- جلد میں جہاں گڑھے، گاڑھی یا جلد موٹی ہو وہاں انجکشن نہ لگائیں۔
- جہاں جلد نرم ہو، چوٹ لگی ہو، کھردری یا سخت ہو، داغ ہوں یا جلد خراب ہو وہاں انجکشن نہ لگائیں۔
- اگر جلد سے سوئی نکالنے کے بعد خون نظر آئے تو انجکشن کی جگہ کو ہلکے سے دبائیں، جگہ کو نہ رگڑیں۔
- اپنی سوئی یا پین کو کسی دوسرے شخص کو استعمال کرنے نہ دیں۔ سوئی کو دوبارہ استعمال نہ کریں۔ کبھی بھی مڑی ہوئی یا خراب سوئی کا استعمال نہ کریں۔
- ٹرزی سلوشن فار انجکشن کو منجمد ہونے سے بچائیں۔ اگر دوا منجمد ہو جائے تو استعمال نہ کریں۔
- غیر استعمال شدہ پین کو فریج میں ۲°C سے ۸°C ڈگری سینٹی گریڈ درجہ حرارت پر رکھیں۔ اگر غیر استعمال شدہ پین کو ۳۰°C ڈگری سینٹی گریڈ درجہ حرارت تک رکھا گیا ہے تو اسے ۳۰ دن کے بعد ضائع کر دیں۔
- گرمی اور روشنی سے بچائیں۔ پین کو روشنی سے بچانے کے لئے ڈبے میں رکھیں۔
- استعمال شدہ پین کو ۲°C سے ۸°C ڈگری سینٹی گریڈ درجہ حرارت یا ۳۰°C ڈگری سینٹی گریڈ درجہ حرارت تک رکھا جا سکتا ہے۔ استعمال شدہ پین کو ۳۰ دن کے بعد ضائع کر دیں۔
- **اگر پین خشک سطح پر گر جائے تو اس پین کو استعمال نہ کریں۔**
- ہر خوراک کے لئے ہمیشہ نئی سوئی کا استعمال کریں تاکہ اس بات کو یقینی بنایا جا سکے کہ سوئی جراثیم سے پاک ہو اور خراب سوئی کے استعمال سے بچا جائے۔ پین کو سوئی لگا کر نہ چھوڑیں۔
- پچھلی خوراک (ایک ماہ کا علاج) کے بعد آپ کو پین میں کچھ دوا باقی نظر آئے تو یہ عام بات ہے۔ باقی رہ جانے والی دوا اس بات کو یقینی بناتی ہے کہ پین درست طریقے سے کام کرتا ہے۔
- اگر چوتھے پین میں ابھی دوا باقی ہے، پھر بھی اسے استعمال نہ کریں۔ چوتھی خوراک کے بعد پین خود بخود لاک ہو جائے گا اور آپ کو مزید مکمل خوراک لینے سے روک دے گا۔

How To Use

ONCE A WEEK

TIRZEE 4 (TIRZEPATIDE) DOSES

ٹرزی 4 ڈوزز

2.5mg/0.6mL, 5mg/0.6mL, 7.5mg/0.6mL, 10mg/0.6mL, 12.5mg/0.6mL & 15mg/0.6mL

Multidose Prefilled Pen
Solution for Injection

DESCRIPTION

Tirzee (Tirzepatide) injection, for subcutaneous use, contains Tirzepatide, a once weekly GIP receptor and GLP-1 receptor agonist. Tirzepatide is based on the GIP sequence and contains aminoisobutyric acid (Aib) in positions 2 and 13, a C-terminal amide, and Lys residue at position 20 that is attached to 1,20-eicosanedioic acid via a linker. Its molecular formula is $C_{225}H_{348}N_{48}O_{68}$.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Tirzee (Tirzepatide) Solution for Injection is available for subcutaneous administration as:

Tirzee Multidose Prefilled Pen 2.5mg/0.6mL
Each 0.6mL dose contains:
Tirzepatide… 2.5mg
Each Pen contains 10mg of Tirzepatide in 2.4mL

Tirzee Multidose Prefilled Pen 5mg/0.6mL
Each 0.6mL dose contains:
Tirzepatide… 5mg
Each Pen contains 20mg of Tirzepatide in 2.4mL

Tirzee Multidose Prefilled Pen 7.5mg/0.6mL
Each 0.6mL dose contains:
Tirzepatide… 7.5mg
Each Pen contains 30mg of Tirzepatide in 2.4mL

Tirzee Multidose Prefilled Pen 10mg/0.6mL
Each 0.6mL dose contains:
Tirzepatide… 10mg
Each Pen contains 40mg of Tirzepatide in 2.4mL

Tirzee Multidose Prefilled Pen 12.5mg/0.6mL
Each 0.6mL dose contains:
Tirzepatide… 12.5mg
Each Pen contains 50mg of Tirzepatide in 2.4mL

Tirzee Multidose Prefilled Pen 15mg/0.6mL
Each 0.6mL dose contains:
Tirzepatide… 15mg
Each Pen contains 60mg of Tirzepatide in 2.4mL

CLINICAL PHARMACOLOGY

Mechanism of Action

Tirzepatide is a GIP receptor and GLP-1 receptor agonist. It is an amino-acid sequence including a C20 fatty diacid that enables albumin binding and prolongs the half-life. Tirzepatide selectively binds to and activates both the GIP and GLP-1 receptors, the targets for native GIP and GLP-1. Tirzepatide enhances first-and second-phase insulin secretion, and reduces glucagon levels, both in a glucose-dependent manner. In addition, both GIP and GLP-1 receptors are expressed in the areas of the brain important to appetite regulation.

Pharmacokinetics

Absorption

Following subcutaneous administration, the time to maximum plasma concentration of Tirzepatide ranges from 8 to 72 hours. The mean absolute bioavailability of Tirzepatide following subcutaneous administration is 80%. Similar exposure was achieved with subcutaneous administration of Tirzepatide in the abdomen, thigh, or upper arm.

Distribution

The mean apparent steady-state volume of distribution of Tirzepatide following subcutaneous administration in patients with type 2 diabetes mellitus is approximately 10.3L and 9.7L in patients who are overweight or have obesity. Tirzepatide is highly bound to plasma albumin (99%).

Metabolism

Tirzepatide is metabolized by proteolytic cleavage of the peptide backbone, beta-oxidation of the C20 fatty diacid and amide hydrolysis.

Elimination

The apparent population mean clearance of Tirzepatide is 0.061L/h with an elimination half-life of approximately 5 days, enabling once-weekly dosing. The primary excretion routes of Tirzepatide metabolites are via urine and feces. Intact Tirzepatide is not observed in urine or feces.

THERAPEUTIC INDICATIONS

Adult

Type 2 Diabetes Mellitus

Tirzee (Tirzepatide) is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications.
- in addition to other medicinal products for the treatment of diabetes.

Cardiovascular Events

Tirzee (Tirzepatide) is indicated to reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction (MI), or nonfatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.

Weight Management

Tirzee (Tirzepatide) is indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.

Obstructive Sleep Apnea (OSA)

Tirzee (Tirzepatide) is indicated in combination with a reduced-calorie diet and increased physical activity to treat moderate to severe Obstructive Sleep Apnea (OSA) in adults with obesity.

Pediatric

Type 2 Diabetes Mellitus

Tirzee (Tirzepatide) is indicated as an adjunct to diet and exercise to improve glycemic control in pediatric patients 10 years of age and older with type 2 diabetes mellitus.

DOSAGE & ADMINISTRATION

- The starting dose of Tirzee (Tirzepatide) is 2.5mg once weekly. After 4 weeks, the dose should be increased to 5mg once weekly. If needed, dose increases can be made in 2.5mg increments after a minimum of 4 weeks on the current dose.
- Consider treatment response and tolerability when selecting the maintenance dosage. If patients do not tolerate a maintenance dosage, consider a lower maintenance dosage.
- The maximum dose is 15mg once weekly.

Recommended Maintenance and Maximum Dosage

Recommended Maintenance Dosage

Adults

Type 2 Diabetes Mellitus, Cardiovascular Events & Weight Management

The recommended maintenance dosage of Tirzee (Tirzepatide) is 5mg, 10mg, or 15mg injected subcutaneously once weekly.

Children and Adolescents Aged 10 to Less Than 18 Years for the Treatment of Type 2 Diabetes Mellitus

The recommended maintenance dosage of Tirzee (Tirzepatide) is 5mg & 10mg injected subcutaneously once weekly.

Obstructive Sleep Apnea (OSA)

The recommended maintenance dosage of Tirzee (Tirzepatide) is 10mg or 15mg injected subcutaneously once weekly.

Maximum Recommended Dosage

The maximum dosage of Tirzee (Tirzepatide) for all indications is 15mg injected subcutaneously once weekly in adults. The maximum dose of Tirzee (Tirzepatide) is 10mg injected subcutaneously once weekly in pediatric patients.

Important Administration Instructions

- Prior to initiation, train patients and caregivers on proper injection technique. A patient may self-inject if a healthcare provider determines that it is appropriate.
- When Tirzee (Tirzepatide) is added to existing metformin and/or sodium-glucose co-transporter 2 inhibitor (SGLT2i) therapy, the current dose of metformin and/or SGLT2i can be continued.
- When Tirzee (Tirzepatide) is added to existing therapy of a sulphonylurea and/or insulin, a reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea and insulin. A stepwise approach to insulin reduction is recommended.
- Administer Tirzee (Tirzepatide) once weekly, any time of day, with or without meals.
- Inject Tirzee (Tirzepatide) subcutaneously in the abdomen, thigh, or upper arm or another person should inject in the back of the upper arm.
- Rotate injection sites with each dose.
- Inspect Tirzee (Tirzepatide) visually before use. It should appear clear and colorless to slightly yellow. Do not use Tirzee (Tirzepatide) if particulate matter or discoloration is seen.
- When using Tirzee (Tirzepatide) with insulin, administer as separate injections and never mix. It is acceptable to inject Tirzee (Tirzepatide) and insulin in the same body region, but the injections should not be adjacent to each other.
- Tirzee (Tirzepatide) is not recommended for self-administration by pediatric patients.
- Tirzee (Tirzepatide) is not recommended for self-administration by those who are visually impaired.

Missed doses

If a dose is missed, it should be administered as soon as possible within 4 days after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

Changing the dosing schedule

The day of weekly administration can be changed, if necessary, as long as the time between two doses is at least 3 days.

Special Population

Patients with Renal Impairment

No dose adjustment is required for patients with renal impairment including End Stage Renal Disease (ESRD). Experience with the use of Tirzee (Tirzepatide) in patients with severe renal impairment and ESRD is limited. Caution should be exercised when treating these patients with Tirzepatide.

Patients with Hepatic Impairment

No dose adjustment is required for patients with hepatic impairment. Experience with the use of Tirzee (Tirzepatide) in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with Tirzee (Tirzepatide).

Pediatric Population

The safety and efficacy of Tirzepatide have not been established in children aged less than 10 years for treatment of type 2 diabetes mellitus and in children and adolescents aged less than 18 years for weight management.
In children weighing < 60kg, caution is advised when escalating to the 10mg dose, since safety data are limited.

Elderly

Only very limited data are available for patient aged ≥ 85 years.

Patients should be advised to carefully read the instructions for use included with the package leaflet before administering the medicinal product.

ADVERSE REACTIONS

Very common:

Hypoglycemia when used with sulphonylurea or insulin, nausea, fatigue, diarrhoea, decreased appetite, vomiting, abdominal pain and constipation.

Common:

Hypersensitivity reactions, hypoglycaemia when used with metformin and SGLT2i, dizziness, hypotension related event, dyspepsia, abdominal distention, eructation, flatulence, gastroesophageal reflux disease, hair loss, injection site reactions, heart rate increased, lipase increased, amylase increased, blood calcitonin increased, cholecystitis and cholelithiasis.

Uncommon:

Hypoglycaemia when used with metformin, weight decreased, dysgeusia, dysaesthesia, acute pancreatitis, delayed gastric emptying and injection site pain.

Rare:

Anaphylactic reaction and angioedema.

"To report SUSPECTED ADVERSE REACTIONS to Getz Pharma's Pharmacovigilance Section, please contact at dsafety@getzpharma.com or +92-21-38636363"

CONTRAINDICATIONS

Tirzepatide is contraindicated in patients with:

- Known serious hypersensitivity to Tirzepatide or to any of the excipients of product.
- A personal or family history of Medullary Thyroid Carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

PRECAUTIONS

WARNING: RISK OF THYROID C-CELL TUMORS

- In both male and female rats, Tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Tirzepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of Tirzepatide-induced rodent thyroid C-cell tumors has not been determined.
- Tirzepatide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Tirzepatide and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Tirzepatide.

Risk of Thyroid C-Cell Tumors

It is unknown whether Tirzepatide causes thyroid C-cell tumors, including Medullary Thyroid Carcinoma (MTC), in humans as the human relevance of Tirzepatide-induced rodent thyroid C-cell tumors has not been determined.
Tirzepatide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors.

Acute Pancreatitis

Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, or Tirzepatide. After initiation of Tirzepatide, observe patients carefully for signs and symptoms of acute pancreatitis, which may include persistent or severe abdominal pain (sometimes radiating to the back) and which may or may not be accompanied by nausea or vomiting. If pancreatitis is suspected, discontinue Tirzepatide and initiate appropriate management.

Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin

Patients receiving Tirzepatide in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia.
The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Hypersensitivity Reactions

If hypersensitivity reactions occur, discontinue use of Tirzepatide; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous serious hypersensitivity reaction to Tirzepatide or to any of the excipients used in Tirzepatide Injection.

Acute Kidney Injury Due to Volume Depletion

There have been postmarketing reports of acute kidney injury, in some cases requiring hemodialysis, in patients treated with GLP-1 receptor agonists, or Tirzepatide. The majority of the reported events occurred in patients who experienced gastrointestinal adverse reactions leading to dehydration such as nausea, vomiting, or diarrhea. Monitor renal function in patients reporting adverse reactions to Tirzepatide that could lead to volume depletion, especially during dosage initiation and escalation of Tirzepatide.

Severe Gastrointestinal Adverse Reactions

Use of Tirzepatide has been associated with gastrointestinal adverse reactions, sometimes severe. Severe gastrointestinal adverse reactions have also been reported postmarketing with GLP-1 receptor agonists. Tirzepatide is not recommended in patients with severe gastroparesis.

Diabetic Retinopathy Complications in Patients with a History of Diabetic Retinopathy

Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Acute Gallbladder Disease

Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Pulmonary Aspiration During General Anesthesia or Deep Sedation

Cases of pulmonary aspiration have been reported in patients receiving GLP-1 receptor agonists undergoing general anaesthesia or deep sedation. Therefore, the increased risk of residual gastric content due to delayed gastric emptying should be considered prior to performing procedures with general anaesthesia or deep sedation.

Suicidal Behavior and Ideation

Suicidal behavior and ideation have been reported in clinical trials with other chronic weight management products. Monitor patients treated with Tirzepatide for the emergence or worsening of depression, suicidal thoughts or behaviors, and/or any unusual changes in mood or behavior. Discontinue Tirzepatide in patients who experience suicidal thoughts or behaviors. Avoid Tirzepatide in patients with a history of suicidal attempts or active suicidal ideation.

Never Share a Tirzepatide Multidose Prefilled Pen Between Patients

Never share Tirzepatide Multidose Prefilled Pen between patients, even if the pen needle is changed. Sharing poses a risk for transmission of blood-borne pathogens.

Effects on ability to drive and use machines

Tirzepatide has no or negligible influence on the ability to drive or use machines. When Tirzepatide is used in combination with a sulphonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines.

Pregnancy

There are no or a limited amount of data from the use of Tirzepatide in pregnant women. Tirzepatide is not recommended during pregnancy and in women of childbearing potential not using contraception. If a patient wishes to become pregnant, or pregnancy occurs, Tirzepatide should be discontinued. Tirzepatide should be discontinued at least 1 month before a planned pregnancy due to the long half-life.

Nursing Mothers

The concentration of Tirzepatide in breastmilk was found to be undetectable to very low (<10ng/ml) compared to plasma concentrations following a single 5mg dose. As Tirzepatide is an amino acid sequence, any low amount present in breastmilk is expected to be degraded and not orally absorbed as intact drug by the breastfed infant. It is not known whether the reduced maternal food intake caused by Tirzepatide affects composition or nutrient content of the breast milk. Overall, Tirzepatide could be considered for use during breast-feeding.

DRUG INTERACTIONS

Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin

When initiating Tirzepatide, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia.

Oral Medications

Tirzepatide delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Tirzepatide.

Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin, digoxin) when concomitantly administered with Tirzepatide.
Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method, or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with Tirzepatide. Hormonal contraceptives that are not administered orally should not be affected.

OVERDOSAGE

In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. Patients may experience gastrointestinal adverse reactions including nausea. There is no specific antidote for overdose of Tirzepatide. A prolonged period of observation and treatment of these symptoms may be necessary, taking into account the half-life of Tirzepatide (approximately 5 days).

STORAGE

Store unused pen in refrigerator at 2°C - 8°C. Protect from heat & light.
If stored at room temperature (up to 30°C), discard unopened pen after 30 days.
Do not freeze. Do not use if it has been frozen.
Used pen may be stored in refrigerator at 2°C - 8°C or at room temperature (up to 30°C).
Discard the pen you are using after 30 days or after taking 4 weekly doses, even if it still has medicine left in it.
Keep out of reach of children.
If you drop the multidose pen on a hard surface, do not use it.
Store pen in the original carton to protect from light.

The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

Tirzee (Tirzepatide) Solution for Injection 2.5mg/0.6mL is available in pack of 1 Multidose Prefilled Pen with 4 needles.
Tirzee (Tirzepatide) Solution for Injection 5mg/0.6mL is available in pack of 1 Multidose Prefilled Pen with 4 needles.
Tirzee (Tirzepatide) Solution for Injection 7.5mg/0.6mL is available in pack of 1 Multidose Prefilled Pen with 4 needles.
Tirzee (Tirzepatide) Solution for Injection 10mg/0.6mL is available in pack of 1 Multidose Prefilled Pen with 4 needles.
Tirzee (Tirzepatide) Solution for Injection 12.5mg/0.6mL is available in pack of 1 Multidose Prefilled Pen with 4 needles.
Tirzee (Tirzepatide) Solution for Injection 15mg/0.6mL is available in pack of 1 Multidose Prefilled Pen with 4 needles.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

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