Dated: 18-08-2026

Artwork: LL-WF-260818A

14inchx6.5inch

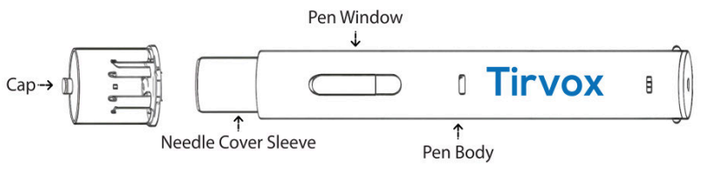
ٹِروکس (ٹرزیپاٹائیڈ)

سنگل ڈوز پری فلڈ پین آٹو انجیکٹر

Tirvox (Tirzepatide)

Single Dose Pre-Filled Pen Autoinjector

INSTRUCTION MANUAL

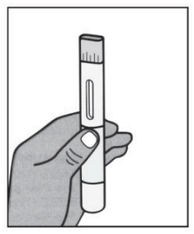


ہدایت نامہ

STEP 1 CHECK THE PEN BEFORE USING

پہلا مرحلہ: استعمال سے پہلے پین کی جانچ کریں۔

1. Hold the Pen in up-right position.
2. Make sure the pen is not damaged and locked properly.
3. Make sure from the pen window that the medicine
   * is not frozen
   *is not cloudy
   *does not have particles



۱ پین کو سیدھا پکڑیں۔

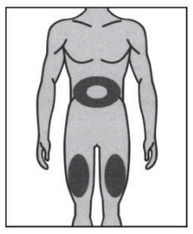
۲ اس بات کو یقینی بنائیں کہ پین خراب نہ ہو اور بند ہو۔

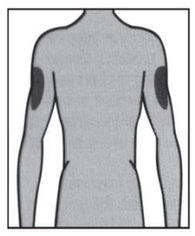
۳ پین ونڈو سے دوا کو دیکھ کر یقینی بنائیں کہ:
* منجمد نہ ہو۔
* گدلا پن نہ ہو۔
* کوئی ذرات موجود نہ ہو۔

STEP 2 CHOOSE YOUR INJECTION SITE

دوسرا مرحلہ: انجکشن لگانے کی جگہ کا انتخاب کریں۔

1. Tirvox can be injected under the skin of stomach area (abdomen), thighs or with the help of someone else at the back of upper arm (as shown in images)
2. Choose a different injection site for each new injection atleast 1-inch from the last area you injected.





۱ ٹرو کس کو پیٹ کے اردگرد، رانوں پر یا کسی اور کی مدد سے بازو کے پچھلے اوپری حصے پر ذیر جلد لگایا جاسکتا ہے۔

۲ ہر دفعہ لگانے سے پہلے تقریباً ایک انچ کا فاصلہ دیں پہلے لگائی ہوئی جگہ سے۔

STEP 3 INSTRUCTIONS TO USE PEN

تیسرا مرحلہ: پین کو استعمال کرنے کا طریقہ۔

1. Remove the pen cap.
2. The needle is hidden, be careful not to push down on the needle cover to avoid needle stick injuries.



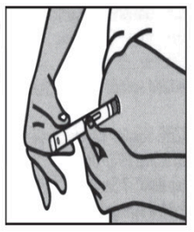
۱ پین کے کیپ کو ہٹائیں۔

۲ سوئی پین کے اندر موجود ہے، سوئی کی چوٹ سے بچنے کیلئے احتیاط کریں کہ سوئی کے کور کو نیچے نہ کیا جائے۔

STEP 4 INJECT THE DOSE

چوتھا مرحلہ: انجکشن لگانے کا طریقہ۔

1. Push the pen (needle cover sleeve) against the skin & keep applying pressure.
2. Listen for click sound during the injection and hold for approximately 10-15 seconds.
3. It is completely injected when the plunger rod entirely covers the pen window.
4. After using the injection, reattach the pen cap & dispose of the used pen.

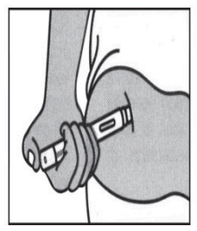


۱ پین کی سوئی کے حفاظتی کور کو اپنے جلد کے مخالف مضبوطی سے دبائیں اور دباؤ کو مسلسل برقرار رکھیں۔

۲ انجکشن لگانے کے دوران کلک کی آواز سنے اور تقریباً 10-15 سیکنڈ تک انتظار کریں۔

۳ جب پین کی ونڈو پر پلنجر راڈ مکمل نظر آجائے تو یہ نشاندہی ہے کہ انجکشن مکمل لگ گیا ہے۔

۴ انجکشن لگانے کے بعد پین کے کیپ کو واپس لگائیں اور استعمال شدہ پین ضائع کردیں۔



IMPORTANT INSTRUCTIONS:

1. Do not inject where the skin has pits, lumps or thickened.
2. Rotate the injection site within the area you choose for each dose to reduce the risk of getting pits in skin or lumps at injection site.
3. Do not inject where the skin is tender, bruised or damaged.
4. If you see blood after taking the needle out of the skin, lightly press the injection site & do not rub.
5. Do not freeze.

ضروری ہدایت :

۱۔ جلد میں جہاں گڑھے، موٹی ہو یا گانٹھیں ہو وہاں انجکشن نہ لگائیں۔

۲۔ اپنی انجکشن کی جگہ کو ہر بار تبدیل کریں تاکہ انجکشن کی جگہوں میں گڑھے یا موٹی ہونے کے خطرے کو کم کیا جاسکے۔

۳۔ جہاں جلد نرم ہو، چوٹ لگی ہو یا خراب ہو وہاں انجکشن نہ لگائیں۔

۴۔ اگر جلد سے سوئی نکالنے کے بعد خون نظر آئے تو انجکشن کی جگہ کو ہلکے سے دبائیں اور رگڑیں نہیں۔

۵۔ دوا کو منجمد ہونے سے بچائیں۔

HORIZON

Tirvox

(Tirzepatide)

2.5mg/0.5ml
5mg/0.5ml
7.5mg/0.5ml
10mg/0.5ml
12.5mg/0.5ml
15mg/0.5ml
Injection
Single Dose Pre-Filled Pen Autoinjector

ٹِروکس

(ٹرزیپاٹائیڈ)

۲.۵ ملی گرام/۰.۵ ملی لیٹر
۵ ملی گرام/۰.۵ ملی لیٹر
۷.۵ ملی گرام/۰.۵ ملی لیٹر
۱۰ ملی گرام/۰.۵ ملی لیٹر
۱۲.۵ ملی گرام/۰.۵ ملی لیٹر
۱۵ ملی گرام/۰.۵ ملی لیٹر
انجکشن
سنگل ڈوز پری فلڈ پین آٹو انجیکٹر

COMPOSITION:
Each single dose pre-filled pen contains:
Tirzepatide……2.5mg in 0.5ml solution
(As per Innovator's Specifications)
(Glass syringe encased in a disposable pre-filled pen)

Each single dose pre-filled pen contains:
Tirzepatide……5mg in 0.5ml solution
(As per Innovator's Specifications)
(Glass syringe encased in a disposable pre-filled pen)

Each single dose pre-filled pen contains:
Tirzepatide……7.5mg in 0.5ml solution
(As per Innovator's Specifications)
(Glass syringe encased in a disposable pre-filled pen)

Each single dose pre-filled pen contains:
Tirzepatide……10mg in 0.5ml solution
(As per Innovator's Specifications)
(Glass syringe encased in a disposable pre-filled pen)

Each single dose pre-filled pen contains:
Tirzepatide……12.5mg in 0.5ml solution
(As per Innovator's Specifications)
(Glass syringe encased in a disposable pre-filled pen)

Each single dose pre-filled pen contains:
Tirzepatide……15mg in 0.5ml solution
(As per Innovator's Specifications)
(Glass syringe encased in a disposable pre-filled pen)

DESCRIPTION:
Tirvox injection, for subcutaneous use, contains tirzepatide, a 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.

EMPIRICAL FORMULA: $C_{223}H_{348}N_{48}O_{68}$
MOLECULAR WEIGHT: 4813.53 Da

CLINICAL PHARMACOLOGY:
MECHANISM OF ACTION:
Tirzepatide is a GIP receptor and GLP-1 receptor agonist. It contains 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. GLP-1 is a physiological regulator of appetite and caloric intake. Nonclinical studies suggest the addition of GIP may further contribute to the regulation of food intake. Both GIP receptors and GLP-1 receptors are found in areas of the brain involved in appetite regulation. Animal studies show that tirzepatide distributes to and activates neurons in brain regions involved in regulation of appetite and food intake.

PHARMACOKINETICS:
The pharmacokinetics of tirzepatide is similar between healthy subjects, patients with overweight or obesity, and patients with OSA and obesity. Steady-state plasma tirzepatide concentrations were achieved following 4 weeks of once weekly administration. Tirzepatide exposure increases in a dose-proportional manner.

ABSORPTION:
Following subcutaneous administration, the median time (range) to maximum plasma concentration of tirzepatide is 24 hours (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 [coefficient of variation (CV)%] apparent steady-state volumes of distribution of tirzepatide following subcutaneous administration in patients with overweight or obesity and patients with OSA and obesity are approximately 9.7 L (29%) and 11.8 L (37%), respectively. 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 in patients with overweight or obesity and patients with OSA and obesity is approximately 0.06 L/h (CV% ~ 20%). The elimination half-life is approximately 5-6 days in patients with overweight or obesity, and in patients with OSA and obesity. The primary excretion routes of tirzepatide metabolites are via urine and feces. Intact tirzepatide is not observed in urine or feces.

INDICATIONS:
Tirvox 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 (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus).
• to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.
• Tirvox is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

LIMITATIONS OF USE:
Tirvox contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.

DOSAGE AND ADMINISTRATION:
RECOMMENDED DOSE ESCALATION SCHEDULE:
• The recommended starting dosage of Tirvox for all indications is 2.5 mg injected subcutaneously once weekly for 4 weeks.
• The 2.5 mg dosage is for treatment initiation and is not approved as a maintenance dosage.
• Follow the dosage escalation below for all indications to reduce the risk of gastrointestinal adverse reactions.
• After 4 weeks, increase the dosage to 5 mg injected subcutaneously once weekly. The dosage may be increased in 2.5 mg increments, after at least 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.

RECOMMENDED MAINTENANCE DOSAGE:
Type 2 Diabetes Mellitus, Weight Reduction and Long-Term Maintenance:
The recommended maintenance dosage is 5 mg, 10 mg, or 15 mg, injected subcutaneously once weekly.

OBSTRUCTIVE SLEEP APNEA (OSA):
The recommended maintenance dosage is 10 mg or 15 mg injected subcutaneously once weekly.

MAXIMUM RECOMMENDED DOSAGE:
The maximum dosage of Tirvox for all indications is 15 mg injected subcutaneously once weekly.

IMPORTANT ADMINISTRATION INSTRUCTIONS:
Prior to initiation, train patients and their caregiver(s) on proper injection technique for the prescribed Tirvox presentation. After training, a patient may self-inject Tirvox if the healthcare provider determines that it can be properly administered, except for the following:
• Inspect Tirvox visually before use. It should appear clear and colorless to slightly yellow. Do not use Tirvox if particulate matter or discoloration is seen.
• Administer Tirvox in combination with a reduced-calorie diet and increased physical activity.
• Administer Tirvox once weekly at any time of day, with or without meals.
• Inject Tirvox subcutaneously in the abdomen, thigh, or another person should inject in the back of the upper arm.
• Rotate injection sites with each dose.

RECOMMENDATIONS REGARDING MISSED DOSE:
• If a dose is missed, instruct patients to administer Tirvox as soon as possible within 4 days (96 hours) 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. The day of weekly administration can be changed, if necessary, as long as the time between the two doses is at least 3 days (72 hours).

CONTRAINDICATIONS:
Tirvox is contraindicated in patients with:
• A personal or family history of MTC or in patients with MEN 2.
• Known serious hypersensitivity to tirzepatide or any of the excipients in Tirvox. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with tirzepatide.

ADVERSE EFFECTS:
It includes Nausea, Vomiting, Diarrhea, Abdominal Pain, Injection Site Reactions, Dyspepsia.

DRUG INTERACTIONS:
CONCOMITANT USE WITH INSULIN OR AN INSULIN SECRETAGOGUE (E.G., SULFONYLUREA):
Tirvox lowers blood glucose. When initiating Tirvox, consider reducing the dose of concomitantly administered insulin or insulin secretagogues (e.g., sulfonylureas) to reduce the risk of hypoglycemia.

ORAL MEDICATIONS:
Tirvox 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 Tirvox.
Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Tirvox.
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 with Tirvox and for 4 weeks after each dose escalation. Hormonal contraceptives that are not administered orally should not be affected.

WARNING & PRECAUTIONS:

WARNING: RISK OF THYROID C-CELL TUMORS

• Tirvox 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 Tirvox 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 Tirvox.

RISK OF THYROID C-CELL TUMORS:
In rats, tirzepatide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) in a 2-year study at clinically relevant plasma exposures. It is unknown whether Tirvox causes thyroid C-cell tumors, including MTC, in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined. Tirvox is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Tirvox 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 Tirvox. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

SEVERE GASTROINTESTINAL ADVERSE REACTIONS:
Use of Tirvox has been associated with gastrointestinal adverse reactions, sometimes severe. In a pool of two Tirzepatide clinical trials for weight reduction (Studies 1 and 2), severe gastrointestinal adverse reactions were reported more frequently among patients receiving Tirzepatide (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1%). Similar rates of severe gastrointestinal adverse reactions were observed in Tirzepatide clinical trials for weight reduction and in Tirzepatide clinical trials for OSA. Tirvox is not recommended in patients with severe gastroparesis.

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 Tirvox. After initiation of Tirvox, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue Tirzepatide and initiate appropriate management.

HYPOGLYCEMIA:
Tirzepatide lowers blood glucose and can cause hypoglycemia. In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m² (Study 2), hypoglycemia (plasma glucose <54 mg/dL) was reported in 4.2% of Tirzepatide -treated patients versus 1.3% of placebo-treated patients. In this trial, patients taking Tirzepatide in combination with an insulin secretagogue (e.g., sulfonylurea) had increased risk of hypoglycemia (10.3%) compared to Tirzepatide -treated patients not taking a sulfonylurea (2.1%). There is also increased risk of hypoglycemia in patients treated with tirzepatide in combination with insulin. Hypoglycemia has also been associated with Tirzepatide and GLP-1 receptor agonists in adults without type 2 diabetes mellitus. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes mellitus, monitor blood glucose prior to starting Tirzepatide and during Tirzepatide treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of insulin or sulfonylurea (or other concomitantly administered insulin secretagogue).

SPECIAL POPULATIONS:
PREGNANCY:
Weight loss offers no benefit to a pregnant patient and may cause fetal harm. Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue Tirvox when a pregnancy is recognized.

CONTRACEPTION:
Use of Tirvox may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. 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 with Tirvox and for 4 weeks after each dose escalation.

LACTATION:
The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tirvox and any potential adverse effects on the breastfed infant from Tirvox or from the underlying maternal condition.

PEDIATRIC USE:
The safety and effectiveness of Tirvox have not been established in pediatric patients.

GERIATRIC USE:
No overall differences in safety or effectiveness have been observed between patients 65 years of age and older and younger adult patients.

RENAL IMPAIRMENT:
No dosage adjustment of Tirvox is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no change in tirzepatide pharmacokinetics (PK) was observed. Monitor renal function in patients reporting adverse reactions to Tirvox that could lead to volume depletion.

HEPATIC IMPAIRMENT:
No dosage adjustment of Tirvox is recommended for patients with hepatic impairment.

OVERDOSAGE:
In the event of an overdosage, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A period of observation and treatment for these symptoms may be necessary, taking into account the half-life of tirzepatide of approximately 5 days.

INSTRUCTIONS:
Store single-dose pen in a refrigerator at 2°C to 8°C. If needed, each single-dose pen can be stored unrefrigerated at temperature not to exceed 30°C for up to 21 days. Discard single-dose pen if not used within 21 days after removing from the refrigerator. Protect from heat, sunlight & moisture. Keep out of the reach of children. To be sold on the prescription of RMP only.

PRESENTATION:
Tirvox (Tirzepatide) 2.5mg/0.5ml Single Dose Pre-Filled Pen Autoinjector is available in 1s.
Tirvox (Tirzepatide) 5mg/0.5ml Single Dose Pre-Filled Pen Autoinjector is available in 1s.
Tirvox (Tirzepatide) 7.5mg/0.5ml Single Dose Pre-Filled Pen Autoinjector is available in 1s.
Tirvox (Tirzepatide) 10mg/0.5ml Single Dose Pre-Filled Pen Autoinjector is available in 1s.
Tirvox (Tirzepatide) 12.5mg/0.5ml Single Dose Pre-Filled Pen Autoinjector is available in 1s.
Tirvox (Tirzepatide) 15mg/0.5ml Single Dose Pre-Filled Pen Autoinjector is available in 1s.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: سنگل ڈوز پین کو فریج میں ۲ ۔ ۸ ڈگری سینٹی گریڈ کے درمیان درجہ حرارت پر رکھیں۔ اگر ضرورت ہو سنگل ڈوز پین کو فریج کے بغیر ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر ۲۱ دن تک رکھا جاسکتا ہے۔ سنگل ڈوز پین فریج سے نکلنے کی صورت میں ۲۱ دن کے اندر استعمال نہ کیا جائے تو ضائع کردیں۔ گرمی دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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