Dated: 07-09-2026

Artwork: LL-WF-260904A

14inchx6.5inch

Tirvox (Multi-Dose)

(Tirzepatide)

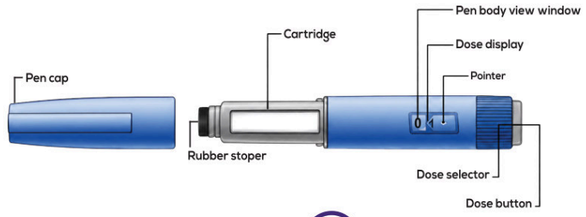
Pre-Filled Pen Autoinjector

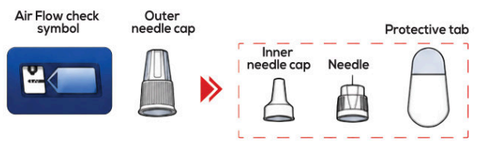
ٹِروکس (ملٹی-ڈوز)

(ٹرزیپاٹائیڈ)

پری فلڈ پین آٹو انجیکٹر

INSTRUCTION MANUAL



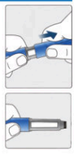


ہدایت نامہ

1 INSPECT THE PEN:

مرحلہ ۱ پین کی جانچ کریں:

1. Pull off pen cap.
2. Make sure from the pen window that the medicine
   - Is not frozen
   - Is not cloudy
   - Does not have particles.



۱۔ پین کے کیپ کو ہٹائیں۔

۲۔ پین ونڈو سے دیکھ کر یقینی بنائیں کہ:

** منجمد نہ ہو۔

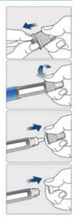
* گدلا پن نہ ہو۔

* کوئی ذرات موجود نہ ہو۔

2 ATTACH THE NEEDLE:

مرحلہ ۲ سوئی کو لگائیں:

1. Remove protective tab from outer needle cap.
2. Push outer needle cap containing the needle straight onto the pen, then screw needle on until secure.
3. Pull off outer needle cap.
4. Pull off inner needle cap. A small drop of liquid may appear. This is normal.



۱۔ سوئی کے بیرونی کیپ سے حفاظتی ٹیب ہٹادیں۔

۲۔ سوئی سمیت بیرونی کیپ کو پین پر سیدھا رکھ کر دبائیں، پھر سوئی کو گھما کر اچھی طرح مضبوط کر دیں۔

۳۔ بیرونی سوئی کا کیپ اتار دیں۔

۴۔ اندرونی سوئی کے کیپ کو اتار دیں: ایک چھوٹی بوند ظاہر ہو سکتی ہے یہ معمولی بات ہے۔

3 PREPARE THE PEN

مرحلہ ۳ پین کو تیار کریں:

1. Hold pen with needle pointing up.
2. Tap cartridge gently with your finger a few times to bring any air bubbles to the top of the cartridge.
3. Select the flow check symbol and press dose button so that drop appears on the tip of needle



۱۔ پین کو اس طرح پکڑیں کہ سوئی اوپر کی طرف ہو۔

۲۔ کارٹرج کو اپنی انگلی سے چند بار ہلکے سے تھپتھپائیں تاکہ ہوا کے بلبلے کارٹرج کے اوپری حصے میں آجائیں۔

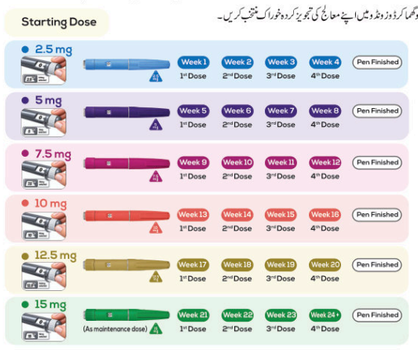
۳۔ فلو چیک کے نشان کو منتخب کریں اور ڈوز بٹن دبائیں تاکہ سوئی کی نوک پر ایک بوند ظاہر ہو جائے۔

4 SELECT THE DOSE:

مرحلہ ۴ خوراک منتخب کریں:

1. Select the dose from the dose window prescribed by the healthcare provider by rotating dose selector.

۱۔ ڈوز سلیکٹر کو گھما کر ڈوز ونڈو میں اپنے معالج کی تجویز کردہ خوراک منتخب کریں۔



5 CHOOSE THE INJECTION SITE:

مرحلہ ۵ انجکشن لگانے کی جگہ کا انتخاب کریں:

1. Choose your injection site in either the stomach (abdomen), thigh, or at the back of upper arm (with the help of someone else).
2. Choose a different injection site for each new injection atleast 1 inch from the last area you injected.



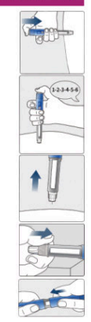
۱۔ انجکشن لگانے کی جگہ کا انتخاب کریں پیٹ، ران یا بازو کے پچھلے اوپری حصے پر (کسی اور کی مدد سے)

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

6 INJECT THE DOSE:

مرحلہ ۶ خوراک انجیکٹ کریں:

1. Place the pen on the injection site.
2. Press the dose button for 6 seconds and inject the dose.
3. Window will return to 0 when the dose is completely injected.
4. Pull the needle out of the skin, a drop of medicine on the needle tip is normal.
5. Put the inner needle cap and throw away the needle.
6. After each use, place the pen cap again.



۱۔ پین کو انجکشن لگانے کی جگہ پر رکھیں۔

۲۔ ڈوز بٹن کو 6 سیکنڈ تک دبائیں اور خوراک انجیکٹ کریں۔

۳۔ جب خوراک مکمل طور پر انجیکٹ ہو جائے گی تو ڈوز ونڈو دوبارہ 0 پر آجائے گی

۴۔ سوئی کو جلد سے باہر نکالیں۔ سوئی کی نوک پر دوا کی ایک بوند کا نظر آنا معمول کی بات ہے۔

۵۔ اندرونی سوئی کا کیپ لگادیں اور سوئی کو ضائع کر دیں۔

۶۔ ہر استعمال کے بعد پین کے کیپ کو دوبارہ لگا دیں۔

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 جمنے سے بچائیں۔

۶۔ ہر انجکشن کیلئے ہمیشہ ایک نئی سوئی استعمال کریں۔

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.
6. Always use a new needle for each injection.

HORIZON

Tirvox (Tirzepatide) 2.5mg 5mg 7.5mg 10mg 12.5mg 15mg Injection Multi-Dose Pre-Filled Pen Autoinjector

ٹِروکس (ٹرزیپاٹائیڈ) ۲.۵ ملی گرام ۵ ملی گرام ۷.۵ ملی گرام ۱۰ ملی گرام ۱۲.۵ ملی گرام ۱۵ ملی گرام انجکشن ملٹی ڈوز پری فلڈ پین آٹو انجیکٹر

COMPOSITION:
Each dose contains 2.5mg of Tirzepatide in 0.6ml solution
Each multi-dose pre-filled pen contains 10mg of Tirzepatide in 2.4ml (4.17mg/ml)
Each pen delivers 4 doses of 2.5mg
(As per Innovator's Specifications)

Each dose contains 5mg of Tirzepatide in 0.6ml solution
Each multi-dose pre-filled pen contains 20mg of Tirzepatide in 2.4ml (8.33mg/ml)
Each pen delivers 4 doses of 5mg
(As per Innovator's Specifications)

Each dose contains 7.5mg of Tirzepatide in 0.6ml solution
Each multi-dose pre-filled pen contains 30mg of Tirzepatide in 2.4ml (12.5mg/ml)
Each pen delivers 4 doses of 7.5mg
(As per Innovator's Specifications)

Each dose contains 10mg of Tirzepatide in 0.6ml solution
Each multi-dose pre-filled pen contains 40mg of Tirzepatide in 2.4ml (16.7mg/ml)
Each pen delivers 4 doses of 10mg
(As per Innovator's Specifications)

Each dose contains 12.5mg of Tirzepatide in 0.6ml solution
Each multi-dose pre-filled pen contains 50mg of Tirzepatide in 2.4ml (20.8mg/ml)
Each pen delivers 4 doses of 12.5mg
(As per Innovator's Specifications)

Each dose contains 15mg of Tirzepatide in 0.6ml solution
Each multi-dose pre-filled pen contains 60mg of Tirzepatide in 2.4ml (25mg/ml)
Each pen delivers 4 doses of 15mg
(As per Innovator's Specifications)

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: C225H348N48O68
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. Tirzepatide enhances first- and second-phase insulin secretion, and reduces glucagon levels, both in a glucose dependent manner.

PHARMACOKINETICS:
The pharmacokinetics of tirzepatide is similar between healthy subjects and patients with type 2 diabetes mellitus. 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 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 10.3 L. 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 primary excretion routes of tirzepatide metabolites are via urine and feces. Intact tirzepatide is not observed in urine or feces. The apparent population mean clearance of tirzepatide is 0.061 L/h with an elimination half-life of approximately 5 days, enabling once-weekly dosing.

INDICATIONS:

DIABETES MELLITUS & CV:
Tirvox is indicated:
• as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.
• to reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction (MI), or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.

WEIGHT MANAGEMENT:
It 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.

DOSAGE AND ADMINISTRATION:

TYPE 2 DIABETES MELLITUS:
Recommended Dosage follow the starting dosage recommendation and dosage escalation schedule below to reduce the risk of gastrointestinal adverse reactions.

RECOMMENDED STARTING DOSAGE AND ESCALATION:
• The recommended starting dosage of Tirvox is 2.5 mg injected subcutaneously once weekly.
• If additional glycemic control is needed, increase the dosage in 2.5 mg increments after at least 4 weeks on the current dose.
• The maximum dosage of Tirvox is:
• 15 mg injected subcutaneously once weekly in adults.
• 10 mg injected subcutaneously once weekly in pediatric patients.

RECOMMENDED STARTING DOSE AND DOSE ESCALATION SCHEDULE FOR WEIGHT MANAGEMENT:
• Start with 2.5mg.
• After 4 weeks, increase the dosage to 5mg injected subcutaneously once weekly. The dosage may be increased in 2.5mg 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:
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.

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:
• Tirvox is not recommended for self-administration by those who are visually impaired.
• Always use a new needle for each injection.
• Administer Tirvox once weekly, any time of day, with or without meals.
• Inject Tirvox subcutaneously in the abdomen, thigh, or have another person inject Tirvox in the back of the upper arm.
• Rotate injection sites with each dose.
• 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.
• When using Tirvox with insulin, administer as separate injections and never mix. It is acceptable to inject Tirvox and insulin in the same body region, but the injections should not be adjacent to each other.

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 medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (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 Tirvox.

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

DRUG INTERACTIONS:
CONCOMITANT USE WITH AN INSULIN SECRETAGOGUE (E.G., SULFONYLUREA) OR WITH INSULIN: When initiating Tirvox, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin 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 and for 4 weeks after each dose escalation with Tirvox. Hormonal contraceptives that are not administered orally should not be affected.

WARNING & 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 Tirvox 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.
• 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:
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.

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 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 Tirvox and initiate appropriate management.

HYPOGLYCEMIA WITH CONCOMITANT USE OF INSULIN SECRETAGOGUES OR INSULIN:
Patients receiving Tirvox 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.

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 Tirvox. 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 Tirvox that could lead to volume depletion, especially during dosage initiation and escalation of Tirvox.

SEVERE GASTROINTESTINAL ADVERSE REACTIONS:
Use of Tirvox has been associated with gastrointestinal adverse reactions, sometimes severe. In the pool of placebo-controlled trials in adults, severe gastrointestinal adverse reactions occurred more frequently among patients receiving Tirvox (5 mg 1.3%, 10 mg 0.4%, 15 mg 1.2%) than placebo (0.9%). Severe gastrointestinal adverse reactions have also been reported postmarketing with GLP-1 receptor agonists. Tirvox is not recommended in patients with severe gastroparesis.

DIABETIC RETINOPATHY COMPLICATIONS IN PATIENTS WITH A HISTORY OF DIABETIC RETINOPATHY: Temporary worsening of diabetic retinopathy has been reported with rapid improvement in glucose control. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

SPECIAL POPULATIONS:
PREGNANCY:
Tirvox should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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 and for 4 weeks after each dose escalation with Tirvox.

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 less than 10 years of age.

GERIATRIC USE:
No overall differences in safety or effectiveness of Tirvox 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 when initiating or escalating doses of Tirvox in patients with renal impairment reporting severe adverse gastrointestinal reactions.

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:
Unopened Multi-Dose Pen: Store unopened multi-dose pen in the refrigerator at 2°C to 8°C. If stored at room temperature up to 30°C, throw away unopened multi-dose pen after 30 days. After Multi-Dose Pen has been opened: Store opened (in-use) multi-dose pen in the refrigerator at 2°C to 8°C or at room temperature up to 30°C. Throw away opened multi-dose pen after a total of 30 days at room temperature, 30 days after first use, or after taking 4 weekly doses, even if there is medicine left in it. Always use a new needle for each injection.Protect from heat, sunlight and moisture. Keep out of the reach of children. To be sold on the prescription of RMP only.

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

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: بھرے ہوئے ملٹی ڈوز پین کو ۲ سے ۸ ڈگری سینٹی گریڈ پر ریفریجریٹر میں رکھیں۔ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھا جائے تو بھرے ہوئے ملٹی ڈوز پین کو ۳۰ دن بعد ضائع کر دیں۔
کھولے گئے ملٹی ڈوز پین کو ۲ سے ۸ ڈگری سینٹی گریڈ پر ریفریجریٹر میں یا ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
کھولے گئے ملٹی ڈوز پین کو ۳۰ دن بعد ضائع کر دیں چاہے اس میں دوا موجود ہو۔ ہر انجکشن کیلئے ہمیشہ ایک نئی سوئی استعمال کریں۔ گرمی، مرطوبیت اور سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف نسخہ (RMP) کے تحت فروخت کریں۔

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