MY TIRZER

Optimized Metabolic **Balanced** Weight

MY TIRZER (Tirzepatide)

Introduction

MY TIRZER (Tirzepatide) is a prescription-only injection medical product indicated for use in combination with diet and exercise to help improve blood sugar control (glycaemic control) in adults.

Tirzepatide is a dual mechanism, activating both Glucose-dependent Insulinotropic Polypeptide (GIP) and Glucagon-Like Peptide-1 (GLP-1) receptors. It enhances metabolic control by increasing insulin secretion in a glucose-dependent manner, reducing appetite, and slowing gastric emptying.

Therapeutic Uses

MY TIRZER is used to:

- **Type 2 Diabetes Mellitus:** Improve blood glucose control in adults, through enhanced insulin secretion and reduced blood sugar levels.
- **Support Weight Management:** Reducing appetite, delaying gastric emptying, and assisting in the maintenance of weight loss in adults with obesity.

MY TIRZER is **not indicated for Paediatric use.** The safety and effectiveness of Tirzepatide in **children and adolescents under 18 years of age** have not been established.

Refer to the **Contraindications** section of this leaflet for further information.

Dosage and Administration

MY TIRZER should be administered as a subcutaneous injection. The dose may vary for each patient. The dosing information provided below represents general recommendations.

Dose Determination

- the strength of the medicine
- the number of doses per week
- the time interval between doses
- the condition being treated

Recommended Dosage

- The recommended starting dosage with 2.5 mg once weekly for 4 weeks for treatment initiation.
- After the initial 4-week period, the weekly dose may be gradually increased in 2.5 mg on the current dose based on tolerability response.
- The maximum recommended dosage is 15 mg once weekly.
- Dose adjustments must be made under the supervision of a healthcare professional.

Missed Dose

- Administered the missed dose as soon as possible within 4 days of the scheduled dose.
- If more than 4 days have elapsed, skip the missed dose and resume the regular dosing schedule.
- **Do not double dose.**

Preparation for administration

- Dilute **MY TIRZER** with 1-2 ml of sterile normal saline for injection.
- Gently swirl the vial until the powder is fully dissolved.
- Withdraw the solution only after complete dissolution.
- An insulin needle (4mm, 31G) is recommended for subcutaneous injection.
- Any unused portion should be stored refrigerated (2°C–8°C) and handled according to storage instructions.
- Do not use the product if it has been frozen.
- Do not mix or dilute **MY TIRZER** with any other medical products or solutions.

Administration

- **MY TIRZER** may be administer at any time of the day, with or without meals.
- Administer by subcutaneous injection into the abdomen, thigh or upper arm.
- Rotate injection sites with each administration to reduce the risk of local reactions.
- **MY TIRZER** must not be administered in combination with other injectable products in the same syringe.
- Patients should be monitored regularly to assess therapeutic response and tolerability.

Contraindications

MY TIRZER must not be used in patients with:

1. History of Medullary Thyroid Carcinoma (MTC).
2. Diagnosis of Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
3. Type 1 Diabetes Mellitus.
4. History of severe gastrointestinal disease (e.g., gastroparesis).
5. History of pancreatitis (acute or chronic).
6. Severe renal impairment or end-stage renal disease.
7. Severe hepatic impairment.
8. Known hypersensitivity to Tirzepatide or any component of the formulation.
9. Pregnancy, breastfeeding, or women planning pregnancy.
10. Age under 18 years.
11. Severely underweight, malnourished, or have active eating disorders (e.g., anorexia nervosa, bulimia)

Possible Side Effects

As with all medicinal products, MY TIRZER may cause side effects, although not all patients will experience them.

Common Adverse Reactions

The following adverse reactions have been commonly reported:

- Nausea
- Vomiting
- Diarrhoea
- Constipation
- Abdominal distension
- Fatigue
- Headache
- Injection-site reactions (including erythema and pruritus)

These reactions are generally mild to moderate and tend to occur during dose escalation.

Possible Side Effects *(continued)*

Serious Adverse Reactions

Seek immediate medical attention if any of the following occur:

- Symptoms suggestive of pancreatitis, including severe and persistent abdominal pain, which may radiate to the back.
- Signs of a serious hypersensitivity reaction, such as swelling of the face, lips, tongue, or throat; difficulty breathing; or widespread rash.
- Severe or persistent gastrointestinal symptoms that may lead to dehydration.
- Clinically significant tachycardia or palpitations.

Clinical Efficacy

Clinical efficacy outcomes are based on controlled clinical trials. Individual patient response may vary.

Glycaemic Control

- In the SURPASS clinical trial programme, Tirzepatide demonstrated substantial reductions in HbA1c compared with active comparators.
- Mean HbA1c reductions ranged from 1.8% to 2.4% from baseline, with a high proportion of patients achieving HbA1c <7.0%.
- A greater proportion of patients achieved glycaemic targets without clinically significant hypoglycaemia.

Weight Management

- Tirzepatide has demonstrated clinically meaningful weight reduction in adults with obesity when used in conjunction with diet and lifestyle modification.
- Clinical Trial Data (SURMOUNT-1): At Week 72, mean percentage body-weight reductions were observed as follows:
  - 15.0% with 5 mg once weekly
  - 19.5% with 10 mg once weekly
  - 20.9% with 15 mg once weekly
  - Compared with 3.1% in the placebo group
- At higher doses, more than 50% of patients achieved ≥ 20% body-weight reduction.
- Significant reductions in waist circumference were observed, consistent with loss of visceral adipose tissue.

Storage

- Store **MY TIRZER** in the **refrigerator at 2°C to 8°C.**
- **Do not freeze.** Protect from light.
- Any remaining solution may be used within 30 days after first opening, provided it has been **stored** properly **under refrigerated conditions.**
- **Keep out of the reach of children.**

Precautions

Regular follow-up with a healthcare professional is required to ensure appropriate therapeutic response and safety. Laboratory monitoring, including blood and urine tests, may be necessary to detect potential adverse effects.

Patients must strictly adhere to instructions provided by their healthcare team, particularly with regard to the following:

Pregnancy & Lactation

- Tirzepatide is not recommended during pregnancy or breastfeeding.
- There are no adequate and well-controlled studies of Tirzepatide use in pregnant women. Animal studies have demonstrated potential fetal harm, including reduced fetal growth.
- It is unknown whether Tirzepatide is excreted in human breast milk. A risk to the breastfed infant cannot be excluded.
- If a patient is pregnant, planning to become pregnant, or suspects pregnancy, Tirzepatide should not be initiated, and the healthcare professional must be informed immediately. Treatment should be discontinued if pregnancy is confirmed.
- In breastfeeding women, a decision should be made to either discontinue breastfeeding or discontinue Tirzepatide treatment, taking into account the benefits of breastfeeding for the child and the benefits of therapy for the mother.

Alcohol

- Consumption of alcohol may increase the risk of hypoglycaemia. Patients should discuss alcohol use with their healthcare professional.

Precautions *(continued)*

Concomitant Medications

- Do not use other medicinal products, including non-prescription medicines, herbal products, or supplements, during treatment with Tirzepatide unless approved by a healthcare professional.
- This includes, but is not limited to, medicines for appetite control, asthma, colds, cough, hay fever, sinus conditions, or salicylates (e.g. aspirin).

Counselling

- Family members or caregivers may require education on recognising and managing potential adverse reactions.
- Patients with diabetes may require counselling regarding dose adjustments related to dietary changes, physical activity, or lifestyle modifications.
- Counselling regarding contraception and pregnancy may be necessary, as diabetes may pose additional risks during pregnancy.

Travel

- Patients should carry a current prescription and relevant medical information at all times.
- Adequate preparation for emergencies is advised.
- When travelling across time zones, efforts should be made to maintain dosing and meal schedules as close as possible to usual routines.

Post-Treatment & Lifestyle Counseling

- Monitor blood glucose levels (particularly in patients with diabetes), blood pressure, and hydration status as clinically appropriate.
- For the first three doses, patients should be observed for 15-30 minutes post-injection to monitor for signs of acute hypersensitivity reactions.
- Patients should be advised to maintain adequate hydration, a balanced diet with sufficient protein and fibre, and engage in regular light-to-moderate physical activity, as appropriate.
- Patients must promptly report any persistent, severe, or worsening adverse reactions to their healthcare professional.
- Disposal: Used vials, syringes, and needles must be disposed of in accordance with local regulations using an approved sharps container.

DISCLAIMER & LEGAL NOTICE

This guideline is provided by Wellnet Xolutions Sdn Bhd as a general reference based on current pharmacological knowledge and accepted clinical practices. The information contained herein, including but not limited to dosing recommendations, storage conditions, and precautions, is intended for use by healthcare professionals only.

The prescribing healthcare professional retains full responsibility for:

1. Conducting a comprehensive patient assessment prior to treatment initiation.
2. Individualising treatment decisions according to the patient's clinical condition and risk profile.
3. Ensuring compliance with appropriate aseptic and sterility procedures.
4. Monitoring therapeutic response and managing any adverse events.

Wellnet Xolutions Sdn Bhd shall not be liable for any clinical outcomes, adverse events, infections, complications, or damages arising from the use, storage, handling, or administration of this product, including decisions made based on this guideline.

This product must be used under the supervision of a qualified healthcare professional. In cases of uncertainty, consultation with relevant specialist references or senior medical professionals is recommended,

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