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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MY TIRZER

Optimumkan Metabolik
Uruskan Berat Badan

MY TIRZER (Tirzepatide)

Pengenalan

MY TIRZER (Tirzepatide) ialah produk perubatan suntikan preskripsi sahaja yang digunakan bersama diet dan senaman untuk membantu meningkatkan kawalan gula darah (kawalan glisemik) dalam kalangan orang dewasa.

Tirzepatide mempunyai mekanisme tindakan dwi, mengaktifkan kedua-dua reseptor Glucose-dependent Insulinotropic Polypeptide (GIP) dan Glucagon-Like Peptide-1 (GLP-1). Ia meningkatkan kawalan metabolik dengan merangsang rembesan insulin secara bergantung kepada glukosa, mengurangkan selera makan dan melambatkan pengosongan gastrik.

Kegunaan Terapeutik

MY TIRZER digunakan untuk:

- **Diabetes Mellitus Jenis 2:** Meningkatkan kawalan glukosa darah dalam kalangan orang dewasa melalui peningkatan rembesan insulin dan pengurangan paras gula darah.
- **Sokongan Pengurusan Berat Badan:** Mengurangkan selera makan, melambatkan pengosongan gastrik, dan membantu mengekalkan penurunan berat badan dalam kalangan orang dewasa dengan obesiti.

MY TIRZER tidak ditunjukkan untuk kegunaan pediatrik. Keselamatan dan keberkesanan Tirzepatide dalam kalangan **kanak-kanak dan remaja di bawah umur 18 tahun** belum ditetapkan.

Sila rujuk bahagian **Kontraindikasi** dalam risalah ini untuk maklumat lanjut.

Dos dan Cara Pemberian

MY TIRZER hendaklah diberikan melalui suntikan subkutaneus (bawah kulit). Dos mungkin berbeza bagi setiap pesakit. Maklumat berikut merupakan cadangan umum.

Penentuan Dos

- Kekuatan ubat
- Bilangan dos setiap minggu
- Selang masa antara dos
- Keadaan yang dirawat

Dos Disyorkan

- Dos permulaan yang disyorkan ialah 2.5 mg sekali seminggu selama 4 minggu.
- Selepas tempoh 4 minggu pertama, dos mingguan boleh ditingkatkan secara beransur-ansur sebanyak 2.5 mg berdasarkan toleransi pesakit.
- Dos maksimum yang disyorkan ialah 15 mg sekali seminggu.
- Pelarasan dos mestilah dilakukan di bawah pengawasan profesional penjagaan kesihatan.

Dos Terlepas

- Ambil dos yang terlepas secepat mungkin dalam tempoh 4 hari dari tarikh dos yang dijadualkan.
- Jika lebih daripada 4 hari telah berlalu, abaikan dos tersebut dan sambung jadual dos biasa.
- **Jangan gandakan dos.**

Penyediaan Sebelum Pemberian

- Cairkan **MY TIRZER** dengan 1–2 ml saline normal steril untuk suntikan.
- Putar vial dengan lembut sehingga serbuk larut sepenuhnya.
- Sedut larutan hanya selepas pembubaran lengkap.
- Jarum insulin (4mm, 31G) disyorkan untuk suntikan subkutaneus.
- Baki yang tidak digunakan hendaklah disimpan dalam peti sejuk (2°C–8°C) dan dikendalikan mengikut arahan penyimpanan.
- Jangan gunakan produk jika telah dibekukan.
- Jangan campur atau cairkan **MY TIRZER** dengan produk perubatan lain atau larutan lain.

Cara Pemberian

- **MY TIRZER** boleh diberikan pada bila-bila masa sepanjang hari, dengan atau tanpa makanan.
- Suntik secara subkutaneus di bahagian abdomen, paha atau lengan atas.
- Tukar lokasi suntikan setiap kali untuk mengurangkan risiko reaksi setempat.
- Jangan campurkan **MY TIRZER** dengan produk suntikan lain dalam picagari yang sama.
- Pesakit hendaklah dipantau secara berkala bagi menilai keberkesanan dan toleransi rawatan.

Kontraindikasi

MY TIRZER tidak boleh digunakan pada pesakit dengan:

1. Sejarah Karsinoma Tiroid Medulari (MTC).
2. Diagnosis Sindrom Neoplasia Endokrin Berganda Jenis 2 (MEN 2).
3. Diabetes Mellitus Jenis 1.
4. Sejarah penyakit gastrousus teruk (contohnya gastroparesis).
5. Sejarah pankreatitis (akut atau kronik).
6. Kerosakan buah pinggang teruk atau penyakit buah pinggang tahap akhir.
7. Kerosakan hati teruk.
8. Hipersensitiviti terhadap Tirzepatide atau mana-mana komponen formulasi.
9. Wanita hamil, menyusu, atau merancang kehamilan.
10. Umur di bawah 18 tahun.
11. Berat badan terlalu rendah, malnutrisi, atau gangguan pemakanan aktif (contohnya anoreksia nervosa, bulimia).

Kesan Sampingan yang Mungkin Berlaku

Seperti semua produk ubat, **MY TIRZER** boleh menyebabkan kesan sampingan, walaupun tidak semua pesakit akan mengalaminya.

Reaksi Advers Biasa

Reaksi buruk berikut telah dilaporkan secara lazim:

- Loya
- Muntah
- Cirit-birit
- Sembelit
- Kembung perut
- Keletihan
- Sakit kepala
- Reaksi di tempat suntikan (termasuk kemerahan dan kegatalan)

Reaksi ini biasanya ringan hingga sederhana dan sering berlaku semasa peningkatan dos.

Kesan Sampingan yang Mungkin Berlaku *(samburg)*

Reaksi Advers Serius

Dapatkan rawatan perubatan segera jika berlaku:

- Gejala pankreatitis seperti sakit perut teruk dan berterusan yang mungkin menjalar ke belakang.
- Tanda reaksi hipersensitiviti serius seperti bengkak muka, bibir, lidah atau tekak, kesukaran bernafas atau ruam menyeluruh.
- Gejala gastrousus teruk atau berpanjangan yang boleh menyebabkan dehidrasi.
- Takikardia atau jantung berdebar yang signifikan secara klinikal.

Keberkesanan Klinikal

Keputusan keberkesanan klinikal adalah berdasarkan kajian klinikal terkawal. Tindak balas individu mungkin berbeza.

Kawalan Glisemik

- Dalam program kajian klinikal SURPASS, Tirzepatide menunjukkan penurunan HbA1c yang ketara berbanding ubat perbandingan aktif.
- Penurunan purata HbA1c adalah antara 1.8% hingga 2.4%. Peratusan tinggi pesakit mencapai HbA1c <7.0%.
- Lebih ramai pesakit mencapai sasaran glisemik tanpa hipoglisemia signifikan secara klinikal.

Pengurusan Berat Badan

- Tirzepatide menunjukkan penurunan berat badan yang bermakna secara klinikal dalam kalangan dewasa obes apabila digunakan bersama diet dan pengubahsuaian gaya hidup.
- Data Kajian Klinikal (SURMOUNT-1) pada Minggu ke-72:
  - 15.0% dengan 5 mg sekali seminggu
  - 19.5% dengan 10 mg sekali seminggu
  - 20.9% dengan 15 mg sekali seminggu
  - Berbanding 3.1% dalam kumpulan plasebo
- Pada dos lebih tinggi, lebih 50% pesakit mencapai ≥20% pengurangan berat badan.
- Pengurangan lilitan pinggang yang signifikan juga diperhatikan.

Penyimpanan

- Simpan **MY TIRZER** dalam **peti sejuk pada suhu 2°C hingga 8°C.**
- **Jangan bekukan.** Lindungi daripada cahaya.
- Larutan yang telah dibuka boleh digunakan dalam tempoh 30 hari jika **disimpan** dengan betul **dalam keadaan sejuk.**
- **Jauhkan daripada capaian kanak-kanak.**

Langkah Berjaga-jaga

Pemantauan berkala oleh profesional penjagaan kesihatan adalah diperlukan untuk memastikan keselamatan dan keberkesanan rawatan. Ujian makmal termasuk ujian darah dan air kencing mungkin diperlukan.

Kehamilan & Penyusuan Susu Ibu

- Tirzepatide tidak disyorkan untuk digunakan semasa kehamilan atau penyusuan susu ibu.
- Tiada kajian yang mencukupi dan terkawal dengan baik mengenai penggunaan Tirzepatide dalam kalangan wanita hamil. Kajian haiwan telah menunjukkan potensi kemudaratan kepada janin, termasuk pengurangan pertumbuhan janin.
- Tidak diketahui sama ada Tirzepatide dikumuhkan ke dalam susu ibu manusia. Risiko kepada bayi yang menyusu tidak dapat diketepikan.
- Jika pesakit sedang hamil, merancang untuk hamil, atau mengesyaki kehamilan, rawatan Tirzepatide tidak boleh dimulakan dan profesional penjagaan kesihatan mesti dimaklumkan dengan segera. Rawatan hendaklah dihentikan jika kehamilan disahkan.
- Bagi wanita yang menyusukan bayi, keputusan perlu dibuat sama ada untuk menghentikan penyusuan susu ibu atau menghentikan rawatan Tirzepatide, dengan mengambil kira manfaat penyusuan kepada bayi dan manfaat rawatan kepada ibu.

Alkohol

- Pengambilan alkohol boleh meningkatkan risiko hipoglisemia.

Langkah Berjaga-jaga *(samburg)*

Ubat Bersama

- Jangan gunakan ubat lain termasuk ubat tanpa preskripsi, produk herba atau suplemen tanpa kelulusan profesional kesihatan.

Kaunseling

- Ahli keluarga atau penjaga mungkin memerlukan pendidikan mengenai pengenalpastian reaksi advers.
- Pesakit diabetes mungkin memerlukan kaunseling berkaitan pelarasan dos akibat perubahan diet atau gaya hidup.
- Kaunseling berkaitan kontraseptif dan risiko kehamilan mungkin diperlukan.

Perjalanan

- Bawa preskripsi semasa dan maklumat perubatan yang berkaitan.
- Pastikan persediaan kecemasan mencukupi.
- Kekalkan jadual dos dan waktu makan sedekat mungkin dengan rutin biasa semasa merentasi zon waktu.

Pemantauan Selepas Rawatan dan Nasihat Gaya Hidup

- Pantau paras gula darah, tekanan darah dan status hidrasi mengikut kesesuaian klinikal.
- Untuk tiga dos pertama, pesakit hendaklah diperhatikan selama 15–30 minit selepas suntikan bagi memantau reaksi hipersensitiviti akut.
- Kekalkan pengambilan air mencukupi, diet seimbang dengan protein dan serat yang mencukupi serta aktiviti fizikal ringan hingga sederhana.
- Laporkan segera sebarang kesan sampingan yang berterusan atau bertambah teruk.
- Pelupusan: Vial, picagari dan jarum terpakai mesti dilupuskan mengikut peraturan tempatan menggunakan bekas sisa tajam yang diluluskan.

PENAFIAN & NOTIS UNDANG- UNDANG

Garis panduan ini disediakan oleh Wellnet Xolutions Sdn Bhd sebagai rujukan umum berdasarkan pengetahuan farmakologi semasa dan amalan klinikal yang diterima. Maklumat ini adalah untuk kegunaan profesional penjagaan kesihatan sahaja.

Profesional penjagaan kesihatan yang memberi preskripsi bertanggungjawab sepenuhnya untuk:

1. Menjalankan penilaian pesakit secara menyeluruh sebelum memulakan rawatan.
2. Menyesuaikan rawatan mengikut keadaan klinikal dan profil risiko pesakit.
3. Memastikan pematuhan kepada prosedur aseptik dan kesterilan yang sesuai.
4. Memantau tindak balas terapeutik dan mengurus sebarang kejadian advers.

Wellnet Xolutions Sdn Bhd tidak akan bertanggungjawab atas sebarang hasil klinikal, kejadian advers, jangkitan, komplikasi atau kerosakan yang timbul daripada penggunaan, penyimpanan, pengendalian atau pemberian produk ini.

Produk ini mesti digunakan di bawah pengawasan profesional penjagaan kesihatan yang berkelayakan. Jika terdapat sebarang keraguan, rujukan kepada pakar berkaitan atau profesional perubatan kanan adalah disyorkan.

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