SUMMARY OF PRODUCT CHARACTERISTICS
Tiza-Q 10 mg/0.5 mL Solution for Injection in Pre-Filled Syringe

1. NAME OF THE MEDICINAL PRODUCT

Tiza-Q 10 mg/0.5 mL Solution for Injection in Pre-Filled Syringe

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL pre-filled syringe contains tirzepatide 10 mg (20 mg/mL).

Excipients with known effect:

Each 0.5 mL dose contains 5.4 mg benzyl alcohol (E1519). This medicinal product contains less than 1 mmol sodium (23 mg) per dose — essentially sodium-free. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection in pre-filled syringe.

A clear, colourless solution, free from visible contaminants, in a 1 mL graduated glass barrel pre-filled syringe. Each pre-filled syringe contains 0.5 mL of solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tiza-Q is indicated in adults:

- For the treatment of insufficiently controlled type 2 diabetes mellitus — as monotherapy when metformin is inappropriate due to intolerance or contraindications, or in addition to other glucose-lowering medicinal products.
- For weight management (weight loss and weight maintenance) as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial BMI ≥30 kg/m² (obesity) or ≥27 to <30 kg/m² (overweight) in the presence of at least one weight-related comorbid condition (hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes or type 2 diabetes mellitus).

4.2 Posology and method of administration

Dose and role of this strength

Tiza-Q 10 mg is a maintenance dose. The starting dose of tirzepatide is 2.5 mg once weekly (use the 2.5 mg strength). After 4 weeks increase to 5 mg once weekly. If additional glycaemic or weight management is needed, further increases in 2.5 mg increments are made after a minimum of 4 weeks on the current dose. The recommended maintenance doses are 5 mg, 10 mg and 15 mg once weekly. The maximum dose is 15 mg once weekly.

Addition to existing therapy

When added to existing metformin and/or SGLT2 inhibitor: continue current dose. When added to a sulfonylurea and/or insulin: consider reducing the dose of the sulfonylurea or insulin to reduce hypoglycaemia risk.

Missed dose

If a dose is missed, administer as soon as possible within 4 days. If more than 4 days have passed, skip the missed dose and resume the normal weekly schedule.

Changing the dosing day

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

Special populations

Elderly, gender, race, ethnicity, body weight: No dose adjustment required. Renal impairment: No dose adjustment required; caution in severe renal impairment/ESRD (limited data). Hepatic impairment: No dose adjustment required; caution in severe hepatic impairment (limited data). Paediatric population (<18 years): Safety and efficacy not established.

Method of administration
Subcutaneous injection in the abdomen, thigh or upper arm. Rotate injection sites with each dose. If also injecting insulin, use a different injection site. May be administered at any time of day, with or without meals. See section 6.6 for instructions for use.

4.3 Contraindications

- Hypersensitivity to tirzepatide or to any of the excipients listed in section 6.1.
- Personal or family history of medullary thyroid carcinoma (MTC).
- Multiple endocrine neoplasia syndrome type 2 (MEN2).

4.4 Special warnings and precautions for use

Thyroid C-cell tumours
In rat carcinogenicity studies, tirzepatide caused an increase in thyroid C-cell tumours at all doses. Human relevance is unknown. Tirzepatide is contraindicated in patients with a personal or family history of MTC or MEN2. Patients should be informed of the potential risk and symptoms of thyroid tumours (neck mass, dysphagia, dyspnoea, hoarseness). Discontinue tirzepatide if MTC is suspected.

Acute pancreatitis
Acute pancreatitis has been reported with tirzepatide. Patients should be informed of the characteristic symptom: persistent severe abdominal pain (often radiating to the back). Discontinue if acute pancreatitis is suspected; do not restart if confirmed. Use with caution in patients with a history of pancreatitis.

Hypoglycaemia
Tirzepatide alone or with agents not causing hypoglycaemia is not associated with hypoglycaemia. When combined with a sulfonylurea or insulin, the risk of hypoglycaemia increases. Consider reducing the dose of the sulfonylurea or insulin.

Gastrointestinal effects
Nausea, vomiting and diarrhoea are common, especially during dose escalation. These may lead to dehydration and renal function deterioration. Advise patients to maintain adequate hydration. Not studied in severe gastroparesis; use with caution.

Diabetic retinopathy
Not studied in patients with non-proliferative DR requiring acute therapy, proliferative DR or DMO; use with caution with appropriate monitoring.

Aspiration risk during procedures
Cases of pulmonary aspiration have been reported in GLP-1 RA patients undergoing general anaesthesia or deep sedation. Consider delayed gastric emptying prior to procedures.

Benzyl alcohol
This medicine contains 5.4 mg benzyl alcohol (E1519) per 0.5 mL dose. Benzyl alcohol may cause allergic reactions. Patients with hepatic or renal impairment should be informed of the potential risk of metabolic acidosis from benzyl alcohol accumulation over time.

Oral contraceptives
Tirzepatide delays gastric emptying and may transiently reduce the rate of absorption of concomitantly administered oral medicines, particularly at initiation. Women using oral contraceptives are advised to switch to a non-oral method, or add a barrier method, upon initiating tirzepatide therapy and for 4 weeks after each dose escalation.

4.5 Interaction with other medicinal products and other forms of interaction

Tirzepatide delays gastric emptying. Effects on rate of absorption of oral medicinal products are most pronounced at initiation of treatment. Monitor patients on oral medications with a narrow therapeutic index (e.g. warfarin, digoxin). Paracetamol: No dose adjustment needed; Cmax reduced 50% and tmax delayed 1 hour with a single 5 mg tirzepatide dose but effect diminished after repeated dosing. Oral contraceptives: Reduced Cmax and AUC at initiation; not considered clinically relevant. Sulfonylureas and insulin: Increased risk of hypoglycaemia — consider dose reduction. Metformin: No dose adjustment required.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies show reproductive toxicity (foetal growth reductions, malformations) at doses below the MRHD. Tirzepatide is not recommended during pregnancy. Women of childbearing potential should use effective

contraception. Discontinue tirzepatide at least 1 month before a planned pregnancy due to the long half-life (approximately 5 days).

Breast-feeding

Unknown whether tirzepatide is excreted in human milk. A risk to the newborn/infant cannot be excluded. A decision should be made whether to discontinue breast-feeding or discontinue tirzepatide.

Fertility

Animal studies did not indicate harmful effects on fertility with tirzepatide.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions were gastrointestinal disorders, mostly mild or moderate in severity. The incidence of nausea, diarrhoea and vomiting was higher during dose escalation and decreased over time.

System Organ Class	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)
Metabolism & nutrition		Hypoglycaemia (with SU/insulin), decreased appetite	DKA (rare)
Nervous system		Dizziness, headache	Dysgeusia
Gastrointestinal	Nausea, diarrhoea, vomiting	Constipation, abdominal pain, dyspepsia, gastro-oesophageal reflux, flatulence, eructation	Acute pancreatitis (rare)
Skin & subcutaneous			Alopecia
Investigations		Elevated lipase, elevated amylase	Tachycardia
Immune system			Hypersensitivity reactions; anaphylaxis, angioedema (rare/post-marketing)
General		Fatigue, injection site reactions	Injection site bruising

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

No human data on overdose of tirzepatide. In the event of overdose, initiate appropriate supportive treatment based on clinical signs and symptoms. Tirzepatide may cause nausea, vomiting and hypoglycaemia in the event of overdose. Monitor the patient clinically and manage symptoms as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in diabetes; glucagon-like peptide-1 (GLP-1) analogues. ATC code: A10BX16.

Tirzepatide is a single peptide that is a dual GIP receptor and GLP-1 receptor agonist (GIPR/GLP-1R agonist). It activates both the GIP receptor and GLP-1 receptor — the two principal incretin receptors — in a glucose-

dependent manner. Activation results in increased insulin secretion, glucagon suppression, slowing of gastric emptying and a feeling of satiety. In 7 completed Phase 3 studies (SURPASS 1–5 and SURMOUNT 1–3), tirzepatide significantly reduced HbA1c (by 1.6–2.4 percentage points) and body weight (by 7–18%) and demonstrated cardiovascular benefits versus comparators including semaglutide and insulin degludec.

5.2 Pharmacokinetic properties

Tirzepatide is an amino acid sequence with a C20 fatty diacid moiety that enables albumin binding and prolongs half-life. Tmax 8–72 hours post subcutaneous dose. Absolute bioavailability approximately 80%. Steady-state exposure achieved after 4 weeks. Tirzepatide exposure increases in a dose-proportional manner. Highly albumin-bound (approximately 99%). Mean apparent volume of distribution approximately 10 L. Metabolised by proteolytic cleavage of the peptide backbone, beta-oxidation of the C20 fatty diacid moiety and amide hydrolysis. Apparent population mean clearance approximately 0.06 L/h; elimination half-life approximately 5 days (consistent with once-weekly dosing). Metabolites excreted via urine and faeces; intact tirzepatide not observed in urine or faeces. Age, gender, race, ethnicity, body weight, renal impairment and hepatic impairment do not have a clinically relevant effect on the pharmacokinetics of tirzepatide.

5.3 Preclinical safety data

No special hazards for humans based on conventional studies of safety pharmacology, repeated dose toxicity or genotoxicity. Rat 2-year carcinogenicity study: thyroid C-cell adenomas and carcinomas at all doses; human relevance unknown. Six-month rasH2 transgenic mouse study: no increased thyroid C-cell tumours. Reproductive toxicity: foetal growth reductions and malformations in rats and rabbits at maternally toxic doses below the MRHD based on AUC. No harmful effects on fertility in animal studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dihydrate, sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), benzyl alcohol (E1519; 5.4 mg per 0.5 mL dose; excipient with known effect), water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, Tiza-Q must not be mixed with other medicinal products.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a refrigerator (2°C–8°C). Do not freeze. Protect from light. Keep out of the reach and sight of children. Once removed from the refrigerator, Tiza-Q may be stored at room temperature (up to 30°C) for up to 30 days.

6.5 Nature and contents of container

Pre-filled glass syringe (single dose) with hidden needle and injection button. Each pre-filled syringe contains 0.5 mL of solution. For single-dose use only.

6.6 Special precautions for disposal and other handling

Inspect Tiza-Q visually before use. Discard if the solution is not clear and colourless or if particulate matter is present. Tiza-Q that has been frozen must not be used. The pre-filled syringe is for single-dose use only. Follow the instructions for use included with the package leaflet carefully. Dispose of used pre-filled syringes in a sharps container in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Q PHARMA DMCC

Unit No. 2681, DMCC Business Centre,

Level 1, Jewellery Complex, Dubai,

P.O. Box 15084, United Arab Emirates.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

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