

## Swiss Medical Hungary Zrt – Patient Information Document

### "Weight Loss with Medical Support" Program

**Mounjaro® 2,5 mg / 5 mg / 7,5 mg / 10 mg / 12,5 mg / 15 mg**

Solution for Injection in Pre-filled Injection Pen / (in certain packages KwikPen or other forms)

#### **0. Important Information Before Starting Treatment**

Dear Patient!

This document is provided as part of Swiss Medical Hungary Zrt private healthcare provider's "Weight Loss with Medical Support" program. Its purpose is to provide you with understandable, yet detailed and verifiable information about:

- The essence of Mounjaro® (tirzepatide), its expected effects, and limitations,
- Possible side effects and warning symptoms,
- Practical information about application (injection),
- Dietary, exercise, and lifestyle conditions that are the foundation of the treatment's effectiveness and safety.

Responsible Information – What Does This Mean?

- Treatment results vary from person to person; Swiss Medical Hungary Zrt does not guarantee results.
- The medication is not a "fat burner" or miracle cure: sustained weight loss requires a calorie deficit, adequate protein intake, and regular exercise.
- Mounjaro® is a prescription medication; its use requires medical decision-making and monitoring.
- This document does not replace a medical visit, individual risk assessment, or the official package insert for the medication. (Swiss Medical Hungary Zrt helps with interpretation within the program framework.)

#### **1. What is Mounjaro® and How Does It Work?**

Mounjaro® contains the active ingredient tirzepatide, which is a dual incretin receptor agonist (GIP and GLP-1 receptor effects). This means the medication mimics and enhances the action of gut hormones that naturally occur in the body and are released after eating. These hormones play a role in appetite regulation, the development of satiety sensation, and the regulation of metabolic processes. Due to tirzepatide's action:

- The brain receives a "fullness" signal faster, therefore hunger sensation decreases,
- A feeling of fullness develops more quickly during meals,
- The amount of food consumed can naturally decrease,
- Gastric emptying slows, so food remains in the stomach longer, which also contributes to the sensation of fullness.

It is important to emphasize that Mounjaro® is not a fat-burning agent, but rather promotes weight loss by helping to regulate appetite and metabolism, making it easier to maintain a calorie deficit.

As a consequence of gut hormone effects, therefore:

- Hunger sensation decreases,
- Satiety feeling develops more quickly,
- The amount of food consumed can decrease,
- Gastric emptying can slow down (this can be significant for side effects and drug interactions). European Medicines Agency (EMA)

⚠ Important: Alongside the medication's effect, you assemble the framework—through daily decisions (diet, exercise, sleep)—that makes weight loss sustainable.

## **2. Who Is Treatment Recommended For / When Should It Be Considered?**

Swiss Medical Hungary Zrt initiates treatment following medical examination, based on individual assessment. The medication's areas of use and the conditions for entering the program are determined based on the current medical status, medical history, laboratory values, and risk profile.

## **3. When Should It NOT Be Used / When Is Heightened Caution Necessary?**

### **3.1 Cannot Be Used (Contraindications)**

- Hypersensitivity to the active substance or any excipient. European Medicines Agency (EMA)

### **3.2 Conditions Requiring Heightened Caution (Important Warnings)**

- Risk of acute pancreatitis (pancreatic inflammation): Acute pancreatitis has been reported with tirzepatide treatment; if suspected, treatment must be suspended, and the medication cannot be restarted after confirmed pancreatitis. European Medicines Agency (EMA)
- Severe gastrointestinal disease / gastroparesis: Caution is advised. European Medicines Agency (EMA)
- Diabetic retinopathy: Tirzepatide has not been studied in certain severe forms of retinopathy (e.g., proliferative, macular edema), so caution and appropriate monitoring are necessary in such cases, and deterioration may occur. European Medicines Agency (EMA)
- Risk of dehydration: In cases of vomiting/diarrhea, fluid and electrolyte loss may occur, which can impair kidney function (potentially up to acute kidney failure). European Medicines Agency (EMA)
- Anesthesia / deep sedation: Due to slowed gastric emptying, the risk of gastric content backup may increase; this must be considered before procedures. European Medicines Agency (EMA)

## **4. Pregnancy, Breastfeeding, Contraception – Critically Important**

### **4.1 Women of Childbearing Age**

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Use of contraception is recommended during tirzepatide treatment. European Medicines Agency (EMA)

#### 4.2 Pregnancy

Tirzepatide is not recommended during pregnancy, and if pregnancy occurs or is planned, treatment must be discontinued; due to the long half-life, it is recommended to stop the medication at least 1 month before planned pregnancy. European Medicines Agency (EMA)

#### 4.3 Breastfeeding

Breastfeeding use requires individual medical consideration (the risk cannot be excluded). European Medicines Agency (EMA)

#### 4.4 Oral Contraceptive – Possible Reduced Effect / Caution

Tirzepatide can slow gastric emptying, which may affect the absorption of certain oral medications. European Medicines Agency (EMA)

In studies with combined oral contraceptives, a reduction in hormone levels was described (C<sub>max</sub> and AUC changes); however, the document notes that this exposure reduction at a single-dose level is not considered clinically relevant, so routine dose adjustment is not necessary. European Medicines Agency (EMA)

Swiss Medical Hungary Zrt Patient Safety Recommendation (Practical):

- Women of childbearing age must always use reliable contraception during treatment. European Medicines Agency (EMA)
- If you are taking oral contraceptives and experience vomiting/diarrhea (which can reduce tablet absorption), supplemental barrier protection (e.g., condom) is recommended during the affected cycle / following days, according to general oral contraceptive guidelines. (Discuss this with your treating physician.)

### 5. **Medication Application – Detailed Practical Guide**

#### 5.1 Method of Administration

- Once weekly, subcutaneous injection (abdomen, thigh, upper arm). European Medicines Agency (EMA)
- The injection can be given at any time of day, regardless of meals. European Medicines Agency (EMA)
- The injection site should be rotated (not always in the same spot). European Medicines Agency (EMA)

#### 5.2 "1-Month Supply" and Needles – What the Pharmacy Should Know

- One device typically contains 4 weeks' worth of doses (one injection per week → 1 month).
- The box typically does not include disposable needles; needles must be requested separately at the pharmacy.

- Example of compatible needle: NovoFine® 6 mm (or equivalent compatible type with the pen).

- Every injection requires a new, sterile needle → 4 needles per box.

⚠ Rule: Reusing needles is prohibited (risk of infection, dulling, inaccurate dosing).

### 5.3 Storage

- Before use, store in refrigerator (2–8 °C), do not freeze. European Medicines Agency (EMA)

- Before first use, allow the preparation to warm to room temperature (approximately 15–30 minutes).

## 6. Possible Side Effects

Like all medications, Mounjaro® can cause side effects, although not everyone experiences them.

### 6.1 Symptoms Requiring Immediate Medical Attention (Serious)

Suspected acute pancreatitis:

- Severe, persistent abdominal pain that may radiate to the back and does not subside.

In such cases, seek medical attention immediately; in case of suspected pancreatitis, treatment must be suspended. European Medicines Agency (EMA)

Severe Allergic Reaction (Rare):

- Difficulty breathing, rapidly developing swelling of face/lips/tongue/throat, difficulty swallowing, severe palpitations → emergency medical care is required. European Medicines Agency (EMA)

### 6.2 Common Side Effects (Most Typical)

The most common side effects are gastrointestinal in nature, particularly during the dose escalation period. European Medicines Agency (EMA)

Very Common / Common (May Occur):

- Nausea, diarrhea, vomiting, abdominal pain, constipation, indigestion (dyspepsia), abdominal bloating, belching, gas production, reflux/GERD. European Medicines Agency (EMA)

- Decreased appetite. European Medicines Agency (EMA)

- Fatigue. European Medicines Agency (EMA)

- Reactions at the injection site (e.g., redness, itching), and injection pain. European Medicines Agency (EMA)

- Dizziness, altered taste (dysgeusia), altered skin sensation (dysesthesia). European Medicines Agency (EMA)

- Increased heart rate, elevated pancreatic enzymes (lipase, amylase) in the blood. European Medicines Agency (EMA)

Gallbladder and Bile Duct Events (Not Common):

- Gallstones (cholelithiasis), gallbladder inflammation (cholecystitis). European Medicines Agency (EMA)

Hypoglycemia (Low Blood Sugar) Risk:

- Risk increases particularly if tirzepatide is used together with insulin or sulfonylurea; in such cases, the physician may consider dose adjustment. European Medicines Agency (EMA)

### 6.3 Diabetic Retinopathy – Possibility of Deterioration

In cases of diabetes-related retinal involvement, retinopathy may worsen, and in certain severe forms, sufficient research data is not available; therefore, heightened caution and monitoring are necessary. European Medicines Agency (EMA)

Signs When to Report:

- Vision impairment, blurred vision, visual field loss, sudden eye-related complaints.

## 7. Lifestyle Program – An Essential Part of Treatment

### 7.1 Basal Metabolic Rate (BMR) – What Is It?

The Basal Metabolic Rate (BMR) is the amount of energy the body uses at rest to maintain vital functions.

Simplified Calculation (Mifflin–St Jeor):

- Women:  $10 \times \text{weight(kg)} + 6.25 \times \text{height(cm)} - 5 \times \text{age} - 161$
- Men:  $10 \times \text{weight(kg)} + 6.25 \times \text{height(cm)} - 5 \times \text{age} + 5$

### 7.2 Total Daily Energy Expenditure (TDEE)

Multiply the BMR by an activity factor:

- Sedentary:  $\times 1.2$
- Lightly active:  $\times 1.375$
- Moderately active:  $\times 1.55$
- Very active:  $\times 1.725$

$TDEE \approx BMR \times \text{activity factor}$

Practical Example:

For a 80 kg weight, 160 cm tall, 50-year-old woman with sedentary work:

$$\begin{aligned} BMR &= 10 \times 80 + 6.25 \times 160 - 5 \times 50 - 161 \\ BMR &= 800 + 1000 - 250 - 161 \\ BMR &\approx 1389 \text{ kcal} \end{aligned}$$

This means the body uses approximately 1389 kcal of energy per day at complete rest.

For a sedentary lifestyle, the activity factor is 1.2:

$$\text{TDEE} \approx 1389 \times 1.2 \approx 1667 \text{ kcal}$$

This is the amount of energy at which body weight would remain approximately unchanged. Weight loss requires consuming fewer calories than this.

Of course, as weight decreases or age changes, these values should be recalculated periodically.

### 7.3 Calorie Deficit – What Does It Mean, and What Is Ideal?

Calorie Deficit: When daily intake is less than daily expenditure (TDEE).

Healthy, sustainable weight loss target:

- Generally approximately 300–500 kcal deficit per day (approximately 0.25–0.5 kg/week),
- With higher body weight, a temporary higher deficit is possible, but excessive deficit increases the risk of muscle loss and weight regain.

Practical Steps (for the Patient):

1. Calculate BMR → TDEE
2. Subtract 300–500 kcal
3. Follow for 2 weeks → measure weight/waist circumference/energy levels
4. If no change: adjust by –100–150 kcal or increase activity

### 7.4 Macronutrient Goals (For Safe Weight Loss)

Protein (Muscle Preservation):

- Typical goal: 1.2–1.6 g/kg body weight/day
- Sources: Lean meats, eggs, fish, cottage cheese/yogurt, legumes

Carbohydrates:

- Primarily slow-absorbing: vegetables, whole grains, legumes
- Avoid: Sugary drinks, sweets, refined baked goods

Fats:

- Unsaturated fats: Olive oil, nuts, avocado, fatty fish

Fiber and Fluid (Especially Important with Mounjaro):

- To prevent constipation: vegetables/fiber + adequate fluid
- In case of vomiting/diarrhea: fluid-electrolyte replacement (consult with physician)

### 7.5 Sample Daily Meal Plans (Examples)

A) 3 Meals / Day (Approximately Moderate Deficit)

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- Breakfast: Greek yogurt + berries + 1 tbsp nuts + cinnamon
- Lunch: Chicken breast/lean turkey + large salad + 1 serving brown rice/quinoa
- Dinner: Salmon/tuna/tofu + steamed vegetables + 1 tsp olive oil

#### B) With 16:8 Intermittent Fasting (2–3 Meals)

- 12:00: Omelet (2–3 eggs) + salad + whole wheat bread (1 slice)
- 16:00: Cottage cheese/protein yogurt + fruit
- 19:30: Lean meat/fish/legumes + vegetables + small serving of carbohydrate

#### C) Vegetarian Day

- Breakfast: Skyr/yogurt or tofu "scramble"
- Lunch: Lentil or chickpea bowl with plenty of vegetables
- Dinner: Cottage cheese/curd + salad + seeds

### 8. Diet-Related Additional Advice, Intermittent Fasting (Time-Restricted Eating) – What Is It Good For, How to Do It, Are There Risks?

What Can It Be Good For?

- Can help reduce the number of meals,
- Structures the day; it can be easier to maintain a calorie deficit.

How to Start Safely?

- Start: 12:12 or 14:10, then after 1–2 weeks, 16:8
- During fasting: Water, sugar-free tea/coffee (individual tolerance varies)
- During eating window: Prioritize protein + vegetables

Possible Risks / When Not Recommended?

- If you are prone to binge eating, suspected eating disorder,
- If daily protein/calories drops too low,
- If there is a high hypoglycemia risk due to diabetes management (medical consultation is necessary).

#### 9. Exercise Program – Gradual Build-up (Detailed)

Foundation Principle: Gradual progression + consistency + muscle preservation

Goal: Reduce fat mass while preserving muscle mass.

Weeks 1–2: "Entry Level"

- Daily 20–30 minutes of easy walking (or 6,000–8,000 steps/day)
- 2× per week, 10–15 minutes of mobilization/stretching

Weeks 3–6: Aerobic + Light Strengthening

- 3–4× per week, 30–40 minutes brisk walking/cycling/swimming
- 2× per week, full-body strengthening (20–30 minutes):
  - Squats to chair, lunges in place, glute bridges
  - Wall/bench push-ups



- Resistance band rows
- Modified plank

From Week 7 Onwards: Sustainable "Baseline"

- 150–300 minutes per week aerobic activity
- 2–3× per week strengthening (progressive: increasing repetitions/weight)

Warning: On days of dizziness, weakness, significant nausea/diarrhea, reduce exercise intensity; fluid replacement is primary.

#### 10. Closing Statement – Patient Safety, Cooperation

Mounjaro® treatment in the Swiss Medical Hungary Zrt program is part of a comprehensive medical and lifestyle program. For the drug's effectiveness and safety, the following are necessary:

- Attending medical appointments,
- Adhering to the prescribed dosing,
- Immediately reporting side effects (in particular: suspected pancreatitis, allergic reaction, vision loss/retinopathy),
- Women of childbearing age using reliable contraception during treatment.