

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

## **Razin Capsules**

Each capsule contains:

Phentermine (as resinate) 15 mg  
Inactive ingredients and allergens in the preparation – see the section "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children and adolescents under the age of 16.

This medicine is usually not intended for adults over the age of 65.

### **1. What is the medicine intended for?**

Razin is intended for the treatment of severe obesity that does not respond to appropriate dietary treatment – a minimum body mass index of 30 kg/m<sup>2</sup> is required.

The treatment should be undertaken under medical supervision and should be based, among other things, on changes in lifestyle, exercise, controlled diet, behavioral support, etc.

**Therapeutic class:** a group of preparations for weight loss that work via the central nervous system.

The medicine directly affects the area in the brain that is responsible for appetite and reduces the feeling of hunger.

### **2. Before using Razin**

**❌ Do not use this medicine if any of the following conditions applies:**

- Sensitivity (allergy) to the active ingredient or to any of the additional ingredients the medicine contains, or to similar medicines used for weight loss. The symptoms of an allergic reaction may be: shortness of breath, wheezing or breathing difficulties, swelling of the face, lips, tongue or other areas in the body, rash, itch, hives.
- In combination with other medicines for weight loss
- Very high blood pressure
- Pulmonary hypertension
- Problems in the heart valves
- A disease associated with the blood vessels in the brain
- A severe heart disease, including arrhythmias
- Narrowing of blood vessels as a result of thickening or hardening of the blood vessels' walls (e.g., atherosclerosis)
- Overactive thyroid
- A psychiatric disease, including anorexia nervosa and depression
- Elevated intraocular pressure (glaucoma)
- You are taking monoamine oxidase inhibitors (for treatment of depression) or two weeks have not yet passed since the termination of treatment
- Drugs and/or alcohol addiction in the past

### **❗ Special warnings regarding the use of the medicine:**

Razin may be used for a period of up to 3 months of treatment.

Weight loss should be gradual and controlled.

Prolonged use may lead to dependence. Do not exceed the recommended dose even if there is no apparent weight loss/continued weight loss. In such cases, contact the treating doctor immediately.

If you are about to undergo surgery, inform the doctor that you are taking Razin.

If you become pregnant during treatment with Razin, inform the doctor immediately. **Before treatment with Razin, inform the doctor if you are:**

- Suffering from:
  - High blood pressure
  - A heart disease, such as angina pectoris
  - Diabetes
  - Epilepsy
- Taking medicines for any other medical condition

### **❗ Drug interactions**

**If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.** Especially if you are taking:

- Other medicines for weight loss
- Antidepressants or medicines for obsessive-compulsive disorder, or for treatment of any other psychiatric disorder
- Ergotamine medicines for treatment of migraine
- Cough and cold medicines
- Thyroid hormones
- Medicines for lowering blood pressure

These medicines may be affected by Razin or may affect its efficacy.

### **❗ Use of the medicine and food**

The preparation should be taken either before breakfast, 1-2 hours after breakfast or 10-14 hours before bedtime.

### **❗ Use of the medicine and alcohol consumption**

Do not drink wine or alcoholic beverages during treatment with this medicine.

Alcohol may increase central nervous system side effects, such as: dizziness and confusion.

### **❗ Pregnancy, breastfeeding and fertility**

You should consult with the doctor if you are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed.

### **❗ Driving and operating machinery**

Use of this medicine may impair alertness and therefore caution should be exercised

when driving a vehicle, operating dangerous machinery and during any activity which requires alertness. Children should be cautioned against riding a bicycle or playing near a road etc.

**❗ Important information about some of the ingredients of the medicine**  
This preparation contains lactose and sucrose. If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.

### **3. How should you use the medicine?**

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is: one capsule before breakfast, or 1-2 hours after breakfast, or 10-14 hours before bedtime.

**Do not exceed the recommended dose.**

### **Duration of treatment**

Razin may be used for a period of up to 3 months of treatment.

### **Method of administration**

The medicine should be swallowed with some water.

Do not open the capsule and scatter its contents, as this is a controlled-release preparation.

**If you accidentally took a higher dosage** the following signs may occur:

Euphoria, nervousness, agitation, disorientation and tremor, muscle spasms and overactive reflexes (hyperreflexia), rapid breathing, confusion, hallucinations, aggressiveness, convulsions, tiredness, anxiety, depression, coma, arrhythmias, an increase or decrease in blood pressure, nausea, vomiting, diarrhea, cramps and abdominal pain.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the

package of the medicine with you.

**If you forgot to take this medicine** in the morning, take it by noon at the latest. If you have failed to take it by noon, skip the dose and take the next dose at the scheduled time on the following day. Taking the medicine later than noon may cause sleep disturbances at night. **Do not take a double dose.**

Follow the treatment as recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.**

**If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

### **4. Side effects**

As with any medicine, use of Razin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

#### Severe side effects

**Refer immediately to a doctor or to an emergency room** if you experience any of the following side effects:

- Heart attack
- Stroke
- Angina pectoris
- Myocardial infarction
- Breathing difficulties

#### Less severe side effects

**Inform the doctor** if you experience any of the following side effects or if they concern you:

- Excessive alertness and sleep disturbances
- Rapid and/or irregular heart rate
- Rise in blood pressure
- Restlessness
- Elated mood followed by despondent mood and tiredness
- Nervousness
- Tremor
- Headache
- Dizziness
- Nausea, vomiting
- Diarrhea or constipation

- Abdominal cramps
- Dry mouth or unpleasant taste
- You cannot exercise like you used to
- Difficulty urinating
- Skin rash
- Impotence
- Changes in sexual drive
- Swelling in the face
- Lower limb edema
- Sudden or rapid weight loss

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.**

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or via the following link:

<https://sideeffects.health.gov.il/>

### **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp.) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Store in the original package.

### **6. Additional information**

In addition to the active ingredient, the medicine also contains: Lactose, Acacia, Sucrose, Magnesium Stearate, Maize Starch, Titanium Dioxide, Yellow Iron Oxide, Black Iron oxide, Red Iron Oxide, Indigo Carmine, Erythrosin, Gelatin.

What does the medicine look like and what are the contents of the package: A Razin capsule has an opaque orange body and an opaque purple cap, and it contains a cream-colored powder with

dark brown beads. Each pack contains blisters of 10 capsules. The amount of capsules in a package: 30 capsules.

**Marketing authorization holder/ manufacturer name and address:** CTS Chemical Industries Ltd., P.O. box 385, Kiryat Malachi.

This leaflet was revised in December 2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 584422492

