



Tracking Sheet

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Contact person: Mor Nitzan
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Project Manager: Erez Hershkovitz
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MyWord Localization hereby certifies that the **English** and **Arabic** text in the following leaflet, is to the best of our knowledge and experience, true and accurate translation of the **Hebrew** text in the same leaflet.

Approved by: Erez Hershkovitz
Date: 28/12/2020

Notes:

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 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 minimal body mass index of 30 kg/m² 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:

- Pregnancy or breastfeeding
- Sensitivity (allergy) to the active ingredient or to any of the additional components 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, itchiness, hives.
- Very high blood pressure
- Pulmonary hypertension
- Problems in the heart valves
- A disease associated with the brain vasculature
- A severe heart disease, including arrhythmias
- Constriction 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
- In combination with other medicines for weight loss

❗ 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 are requested to undergo blood tests, inform the doctor that you are taking Razin, as this may affect the results of certain tests.

If you become pregnant during treatment with Razin, inform the doctor immediately.

❗ Before treatment with Razin, inform the doctor if you have:

- High blood pressure
- A heart disease, such as angina pectoris

- Diabetes
- Epilepsy

❗ Drug-drug interactions

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

- Other medicines for weight loss
- Anti-depressants or medicines for obsessive-compulsive disorder, such as: fluoxetine, sertraline, paroxetine, clomipramine
- Ergotamine medicines for treatment of migraine
- Cough and cold medicines that contain pseudoephedrine, phenylpropanolamine or phenylephrine
- Thyroid hormones
- Any medicines for treatment of a psychiatric disorder
- Medicines for lowering blood pressure including clonidine, methyldopa or guanethidine

These medicines may be affected by Razin or affect its efficacy. It may be necessary to adjust the doses or replace the medicines.

❗ 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

The medicine must not be used when you are pregnant or breastfeeding.

❗ Driving and operating machinery

Use of this medicine may impair alertness and therefore caution should be exercised when driving a car, 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 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

Swallow the medicine with a little water.

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

If you accidentally took a higher dose 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 next 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 the medicine. Wear glasses if you need them. If you have any other questions regarding 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.

Stop using this medicine and refer immediately to a doctor or to an emergency room if you experience any of the following side effects:

Symptoms characteristic of a heart attack, stroke, angina pectoris, myocardial infarction. These side effects are rare.

Inform the doctor immediately if you experience any of the following side effects:

Sudden or rapid weight loss, breathing difficulties, chest pains, fainting, lower limb edema, if you cannot exercise like you used to, dry mouth or unpleasant taste, difficulty urinating, skin rash, impotence, changes in sexual drive, swelling in the face.

Inform the doctor if you experience any of the following side effects or if they concern you: Excessive alertness, sleeping 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.

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), which will direct you to the online form for reporting side effects, or by clicking on 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 lower than 25°C.
- Store in the original package.

6. Additional information

In addition to the active ingredient, the medicine

- حُرْزَنَة في العبُوَّة الأصليَّة.

6. معلومات إضافية

يحتوي الدواء بالإضافة للمادة الفعالة أيضا على:

Lactose, Acacia, Sucrose, Magnesium Stearate, Maize Starch, Titanium Dioxide, Yellow Iron Oxide, Black Iron oxide, Red Iron Oxide, Indigo Carmine, Erythrosin, Gelatin.

يجب المواظبة على العلاج حسب توصية الطبيب.

لا يجوز تناول الأدوية في العتمة! راجع المنصق وتأكد من الجرعة في كل مرّة تتناول فيها الدواء.
ضع النظارات الطبيَّة إذا كنت بحاجة إليها.

إذا توفرت لديك أسئلة إضافية حول استعمال الدواء، فاستشر الطبيب أو الصيدلي.

4. الأعراض الجانبية

مثل كلِّ دواء، قد يؤدي استعمال رازين إلى نشوء أعراض جانبية عند بعض المستعملين. لا تفلق عند قراءة قائمة الأعراض الجانبية. قد لا تعاني من أيِّ واحد منها.

يجب التوقف عن استعمال الدواء والتوجُّه فوراً إلى الطبيب أو إلى غرفة الطوارئ إذا كنت تشعر بأحد الأعراض الجانبية التالية:
أعراض مميزة للوبئة القلبية، سكتة دماغية، ذبحة صدرية، احتشاء عضلة القلب.

هذه الأعراض نادرة.

يجب إخبار الطبيب على الفور إذا كنت تشعر بأحد الأعراض الجانبية التالية:

فقدان فجائيٍّ أو سريع للوزن، صعوبات في التنفُّس، الآم في الصدر، إغماء، وذمة في الطرفين السفليين، إذا لم تعد قادراً على القيام بنشاط بدنيٍّ كما كنت في الماضي، جفاف القدم أو طعم كريه، صعوبات في التبول، طلع جلدي، الضعف الجنسي، تغيرات في الشهوة الجنسية، انتفاخ في الوجه.

يجب إخبار الطبيب إذا كنت تشعر بأحد الأعراض الجانبية التالية أو إذا كانت مزعجة بالنسبة لك:

فرط اليقظة، اضطرابات في النوم، تسارع نظم القلب و/أو عدم انتظامه، ارتفاع ضغط الدم، تململ، مزاج مبهتج يليه مزاج كئيب

وتعب، عصبية، ارتعاش، صداع، دوام، غثيان، تقبُّوات، إسهال أو إمساك، تقلصات في البطن.

إذا ظهر عرض جانبي، إذا تفاقم أحد الأعراض الجانبية أو إذا عانيت من عرض جانبي لم يُذكر في هذه النشرة، فعليك استشارة الطبيب.

بالإمكان التبليغ عن أعراض جانبية لوزارة الصحة بواسطة الضغط على الرابط "التبليغ عن أعراض جانبية عقب العلاج الدوائي" الموجود في الصفحة الرئيسية لموقع وزارة الصحة

(www.health.gov.il) والذي يوجه إلى الاستمارة المُصَّلة للتبليغ عن أعراض جانبية. أو عن طريق الدخول إلى الرابط: https://sideeffects.health.gov.il

5. كيف يجب تخزين الدواء؟

- امنع التسمُّم! هذا الدواء، وكلِّ دواءٍ آخر، يجب حفظه في مكان مغلقٍ بعيداً عن متناول أيدي الأولاد و/أو الأطفال الرضّع ومجال رؤيتهم، وبذلك ستمنع التسمُّم. لا تسيب التقبُّ بدون تعليمات صريحة من الطبيب.
- لا يجوز استعمال الدواء بعد تاريخ انتهاء الصلاحية (exp.) المدوَّن على العبوة. يشير تاريخ انتهاء الصلاحية إلى اليوم الأخير من نفس الشهر.
- يجب التخزين في درجة حرارة أقل من 25 درجة مئوية.



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