

**PATIENT PACKAGE
INSERT ACCORDING TO
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

This medicine can be dispensed with a doctor's prescription only

Permixon® 160 mg

Capsules

Composition:

Active ingredient and its quantity – each capsule contains:

Lipidosterolic Extract of Serenoa Repens 160 mg

Inactive ingredients and allergens in the medicine: see section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It might harm them, even if you think that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of moderate micturition troubles related to benign hypertrophy of prostate in adult men.

Therapeutic group: a medicinal product that is used for the treatment of benign hypertrophy of the prostate.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient Lipidosterolic Extract of Serenoa Repens or to any of the other ingredients contained in the medicine (see section 6).

Special warnings regarding the use of this medicine

- Taking the medicine on an empty stomach may cause nausea.
- While using the medicine it is necessary to monitor your prostate regularly by your

doctor. Under no circumstances may Permixon replace surgery, if surgery is necessary.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription drugs and nutrition supplements, tell the doctor or pharmacist.

Use of this medicine and food
Take this medicine with meals.

Pregnancy, breastfeeding and fertility

This medicinal product is not intended for use in women.

3. HOW TO USE THIS MEDICINE

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage or manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is 2 capsules a day, with meals.

Do not exceed the recommended dose. Take the medicine with meals. Swallow the medicine with a glass of water. Do not open and disperse the contents of the capsule.

If you have accidentally taken a higher dosage, transient gastrointestinal problems (abdominal pain) may occur.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the set time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the doctor or pharmacist.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Permixon 160 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You might not suffer from any of them.

Common side effects (effects that appear in 1-10 users out of 100)

- Headache (migraine)
- Abdominal pain

Uncommon side effects (effects that appear in 1-10 users out of 1,000)

- Nausea
- An increase in the gamma-glutamyltransferase enzyme, a moderate increase in the transaminase enzyme (liver enzymes)
- Urticaria (a skin rash)
- Breast enlargement in men (gynecomastia) – reversible after discontinuing use of the medicine

Side effects whose frequency is unknown (effects whose frequency has not been determined yet)

- Edema (swelling of the skin)

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

Reporting of side effects

Side effects can be reported to the Ministry of Health via the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link:

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

Additionally, it can be reported to Padagis via the following address: Padagis.co.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.

Medicinal products should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicinal products that are no longer required. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Polyethylene glycol 10,000, Gelatine, Titanium dioxide E171, Yellow iron oxide E172, Indigotin E132

What the medicine looks like and contents of the package:
Light green colored capsule.

Packages of 30, 56, 60 and 100 capsules, packed in blister trays. It may be that not all pack sizes are marketed.

Registration Holder, Importer and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

Revised in March 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 11318.28916

Permixon is a registered trademark of Pierre Fabre Medicament.

21.03.2023