SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PERMIXON ®160 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lipidosterolic Extract of Serenoa Repens 160mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Dosage and method of administration

2 capsules a day, at mealtimes, should be taken with a glass of water.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

In accordance with the routine monitoring of benign prostatic hypertrophy, the patient must be under ongoing medical supervision during treatment.

Taking this medicinal product on empty stomach may cause nausea.

4.5 Interactions with other medicinal products and other forms of interaction

Experimental studies with PERMIXON do not show any negative interference with the therapeutic groups commonly associated with this condition (antibiotics for urinary tract infections, antiseptics and anti-inflammatory medicines).

Results from dedicated in vitro studies demonstrated the absence of inhibition and induction potential of lipidosterolic extract of Serenoa repens.

No pharmacokinetic interactions are expected with co-administered treatments.

4.6 Fertility, pregnancy and breastfeeding

Not applicable, as this medicinal product is not indicated in women.

4.7 Effects on ability to drive and use machines

Effects on the ability to drive and use machines have not been studied.

4.8 Undesirable effects

The following table shows the undesirable effects observed in nine clinical studies with a total of 4401 patients: 2428 taking Permixon, for which the assessment of causality was not “excluded”.

The undesirable effects classified by organs or systems (according to the MedDRA system) are listed below as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and frequency unknown (it cannot be estimated on the basis of the data available).

No adverse drug reactions were “very rare”, “rare” or “very common” in frequency and therefore these columns were not presented in the table.

Common >=1% to 10%	**Uncommon >=0.1% to 1%**	**Unknown**
Nervous system disorders		
Headaches		
Gastrointestinal disorders		
Abdominal pain	Nausea	
Hepatobiliary disorders		
	Gamma-glutamyltransferase increased	
	Transaminases increased	
Skin and subcutaneous tissue disorders		
	Rash	
General disorders and administration site conditions		
		Oedema
Reproductive system and breast disorders		
	Gynaecomastia	

During clinical trials, only moderate increases in transaminases was observed and the increase in liver enzymes was of no clinical significance.

Gynaecomastia has been observed but was reversible after treatment discontinuation.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form at http://sideeffects.health.gov.il
In addition, you can report to Padagis via the following address: Padagis.co.il

4.9 Overdose

In the event of overdose, gastrointestinal disorders may occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in Benign Prostatic Hypertrophy, ATC code: G04CX02.
The lipidosterolic extract of Serenoa repens has anti-inflammatory, antiandrogenic and antiproliferative properties that act on benign prostatic hyperplasia.

Anti-inflammatory properties are expressed by an inhibition:

- of phospholipase A2 (reduction of arachidonic acid synthesis),
- of cyclooxygenase (reduction of prostaglandins),
- of lipoxygenase (reduction of leukotrienes.)

This action on the arachidonic acid cascade and the effect observed on some inflammatory cytokines explain the anti-inflammatory activity found both in animal models and benign prostatic hyperplasia.

Antiandrogenic properties are mainly due to an inhibition of the 5 alpha reductases responsible for transforming testosterone into its active metabolite dihydrotestosterone (DHT). This antiandrogenic activity is also increased by a reduction of the prolactin-dependent penetration of testosterone into the cell, an inhibition of oestrogen-dependent androgen receptor formation and finally an inhibition of DHT binding to its receptors.

This activity has been confirmed in an experimental rat model of benign prostatic hyperplasia.
Antiproliferative properties are explained by the fact that the lipidosterolic extract of Serenoa repens slows the proliferation of the glandular epithelium (estimated using the tritium-labelled thymidine index) induced by growth factors in human prostate organotypic cells.

It reduces protein synthesis in prostate cell cultures, stimulated by a combination of testosterone and prolactin, the latter of which regulates prostatic volume.

Lipidosterolic extract of Serenoa repens acts also as a neurogenic inhibitor of α1-adrenergic-induced and thromboxane-induced contractions in prostate tissues, and methacholine-induced and thromboxane-induced contractions in detrusor tissues.

5.2 Pharmacokinetic properties

It is impossible to fully evaluate the pharmacokinetic properties of medicines of this type as it is impossible to determine the concentrations of all plant extract components in the blood.

5.3 Preclinical safety data

Non-clinical data from conventional safety pharmacology, repeat dose toxicity, genetic toxicity and reproductive function and development studies reveal no particular risk for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol 10,000
Composition of the capsule shell: Gelatin, Titanium dioxide E171, Yellow iron oxide E172, Indigotin E132

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25˚C.

6.5 Nature and content of container

Box of 30, 56, 60 or 100 capsules in blister packs (PVC-Aluminum).
Not all packages may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7. LICENSE HOLDER

Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham

8. REGISTRATION NUMBER

113-18-28916

9. DATE OF REVISION OF THE TEXT

Revised in November 2025.

17.11.2025