

## **PROSTAMOL-UNO®**

**INTERNATIONAL NON-PROPRIETARY NAME (INN):** Saw palmetto fruit extract.

### **DOSAGE FORM AND STRUCTURE:**

*Active ingredient:* ethanol extract of *Serenoa repens* fruit (9–11: 1) - 320 mg;

*Excipients (capsule shell):* succinyl gelatin, glycerol, purified water, titanium dioxide, black iron dye, crimson dye [Ponceau 4R].

### **DESCRIPTION:**

Oval, soft, gelatin capsules with a light proof two-coloured red and black shell.

Capsule content: greenish-brown liquid with a specific odor.

**ATC CODE:** G04CX02 *Sabal*is serrulatae fructus.

**PHARMACOLOGICAL ACTION:** plant origin remedy for the treatment of benign prostatic hyperplasia.

### **PHARMACODYNAMICS:**

*Serenoa repens* fruit extract has anti-proliferative, anti-androgenic, anti-inflammatory, and anti-edematous effects, which are selectively manifested in the prostate gland.

The drug does not affect the level of sex hormones in the blood plasma, does not affect potency and libido, and does not change the level of prostate-specific antigen in the blood plasma.

The local antiproliferative effect of the drug is manifested by a decrease in the activity of growth factors (primarily epidermal and fibroblastic), inhibition of the binding of prolactin receptors with a subsequent disruption of signal transmission to the prostate cells and acceleration of the apoptosis of prostate cells, which is reflected in the inhibition of the prostate volume growth.

The mechanism of local antiandrogenic action is due to the inhibition of the synthesis of dihydrotestosterone from testosterone (due to inhibition of the enzyme 5-alpha reductase types I and II) and its fixation to the cytosolic receptors of prostate cells, which prevents the penetration of the hormone into the nucleus. As a result, protein synthesis is reduced.

The mechanism of local anti-inflammatory action is due to the fact that the extract of the saw palmetto fruits (*Serenoa repens*) inhibits the activity of phospholipase A2, 5-lipoxygenase and the release of arachidonic acid, thereby reducing the synthesis of prostaglandins and leukotrienes, which are inflammatory mediators.

Prostamol® Uno reduces capillary permeability and vascular stasis, reduces swelling and inflammation in the prostate, eliminates compression of the bladder neck and urinary tract, improving urodynamics. Thus, Prostamol® Uno helps, on the one hand, to reduce the severity of pathological symptoms of benign prostatic hyperplasia (dysuria, pollakiuria, nocturia, pain and straining to void, incomplete emptying of the bladder) and to increase the volume and strength of urination. On the other hand, with the use of the drug, further growth and an increase in the volume of the prostate gland slows down.

**PHARMACOKINETICS:**

*Serenoa repens* fruit extract is rapidly absorbed. After an oral administration, the maximum plasma concentration is reached after approximately 1.5 hours.

**INTENDED USES:**

- Benign prostatic hyperplasia (stages I and II);
- Elimination of dysuria symptoms (urination disorder, nocturnal pollakiuria, pain syndrome, etc.) in chronic prostatitis.

**CONTRAINDICATIONS:**

Drug components intolerance.

**DOSAGE AND ADMINISTRATION:**

Prostamol® Uno is administered in the dosage of 1 capsule (320 mg) 1 time per day at the same time, after meals, without chewing, with a sufficient amount of liquid. The duration of treatment is not limited in time. The recommended duration of the course of therapy is at least three months.

**PRECAUTION:**

Prostamol® Uno inhibits the severity of symptoms of the enlarged prostate gland without reducing its size. It prevents further proliferation of prostate tissue. Prostamol® Uno does not affect sexual function.

**SIDE EFFECTS:**

Allergic reactions to the components of the drug are possible. In rare cases, there might be discomfort in the gastrointestinal tract: nausea, heartburn (when taken on an empty stomach).

**OVERDOSE:**

There are no cases of overdose with Prostamol® Uno.

**INTERACTION WITH OTHER DRUGS:**

Interaction with other medicinal substances has not been identified.

**INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE****MECHANISMS:**

Prostamol® Uno does not affect the ability to drive vehicles and to perform work requiring increased concentration of attention.

**STORAGE CONDITIONS:**

Store at a temperature not exceeding 25°C (77°F). Keep out of the reach of children.

**SHELF LIFE:**

3 years. Do not use after the expiry date indicated on the package.

**MANUFACTURER:** Berlin-Chemie / A. Menarini, Germany.