ADENOPROSIN®

INTERNATIONAL NON-PROPRIETARY NAME (INN): n/a.

DOSAGE FORM AND STRUCTURE:

Active ingredient: active complex Adenoprosin 150 mg, in terms of the total protein 29 mg. *Excipients*: solid fat - Suppocire AM in the amount which is necessary for obtaining a suppository at the weight of 2000.0 mg

<u>DESCRIPTION:</u> cylindrically shaped suppositories with a color ranging from yellow to brown. Color irregularity in the form of inclusions of a darker color is allowed.

ATC CODE: G04BX Other urologicals.

PHARMACOLOGICAL ACTION: Medication for the treatment of urological diseases.

PHARMACODYNAMICS:

The active substance that is part of Adenoprosin® drug, is a biomass obtained from the insect larvae of the *Lymantria dispar* species, which has an anti-inflammatory and antioxidant effect. Biologically active components of the drug reduce the formation of A2 - phospholipase and the release of arachidonic acid with a decrease in the synthesis of prostaglandins and 1 g of leukotrienes (they inhibit 5-lipoxygenase). The drug reduces the capillary permeability, prostate edema, and improves the microcirculation in the prostate gland. The action of Adenoprosin® is manifested due to pathogenetic and nonspecific mechanisms. Adenoprosin® improves urodynamic parameters (increases the maximum volumetric flow rate of the urine, decreases the urination time, reduces the amount of residual urine) and the general condition of patients with benign prostatic hyperplasia (BPH) and chronic prostatitis (reduces the index of chronic prostatitis, reduces the content of leukocytes in the secretion of the prostate gland, improves the homogeneity of its echostructure). The drug regulates the tone and peristalsis of the lower segments of the urinary tract, reducing the frequency of urination, including at nightime, and reducing dysuric manifestations, a feeling of incomplete emptying of the bladder and the straining to void. The antioxidant effect of Adenoprosin® is expressed through the inhibition of the lipid peroxidation due to the antioxidant water-soluble compounds of the drug.

PHARMACOKINETICS:

The action of Adenoprosin® is a combination of the effects of the biologically active components of the biomass obtained from the insect larvae *Lymantria dispar* species; therefore, pharmacokinetic studies are currently not possible.

INTENDED USES:

- Benign prostatic hyperplasia;
- Chronic prostatitis (in combination therapy).

CONTRAINDICATIONS:

- Hypersensitivity to the drug ingredients;
- Acute urinary retention;
- Children under 18 years old;
- Malignant neoplasms of the prostate gland.

DOSAGE AND ADMINISTRATION:

The drug is administered rectally, one suppository once a day (preferably at the same time, at night). The duration of the treatment is from 1 to 3 months, depending on the intensity of inflammatory processes in the prostate and the severity of symptoms of BPH, as well as their combination. If necessary, the course of treatment can be repeated.

PRECAUTION:

The drug should be administered after the defecation or enema. After the drug administration it is recommended to remain in horizontal position for 30-40 minutes.

SIDE EFFECTS:

In the gastrointestinal tract: rarely - diarrhea or frequent stool; itching in the anal area. Allergic reactions and general weakness are possible.

OVERDOSE:

To date, no cases of overdose have been reported.

INTERACTION WITH OTHER DRUGS:

To date, cases of clinically significant drug interactions of Adenoprosin® with other drugs have not been reported.

PREGNANCY AND LACTATION:

The drug is not intended for women.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:

The drug does not affect the ability to drive vehicles and operate mechanisms.

STORAGE CONDITIONS:

Keep in a dry, dark place, at a temperature below 25°C (77°F). Keep out of the reach of children.

SHELF LIFE:

2 years. Do not use after the expiration date.

MANUFACTURER: Farmaprim LTD. www.farmaprim.md