

Package leaflet: Information for the user

Prostamol Uno 320mg soft capsules thick extract of saw palmetto berries

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Prostamol Uno is and what it is used for
2. What you need to know before you take Prostamol Uno
3. How to take Prostamol Uno
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1. What Prostamol Uno is and what it is used for

Prostamol Uno contains substance thick extract of saw palmetto berries (*Serenoae repentis extractum*) which is a herbal urological medicine (for prostate).

Prostamol Uno is used in adult men to treat micturition disorders (difficulty in emptying the bladder) due to benign prostate enlargement (of non-carcinogenic origin), stage I and stage II.

Classification of the steps of a benign (non-carcinogenic) prostatic hyperplasia

Stages	Name	Features
I	Inflammatory stage of bladder	-delayed onset of urination -prolonged urination and interrupted jet -weak stream during urination -frequent urination (especially at night) -fully emptying the bladder after urination
II	Residual urine stage	-difficulties urinating -the bladder does not empty completely and residual urine is retained even after urinating. The patient has the feeling of incomplete emptying of the bladder.

Benign prostatic hyperplasia may have the following symptoms:

- need for frequent urination, especially at night
- weak and interrupted stream during urination
- incomplete emptying of the bladder
- a feeling of incomplete emptying of the bladder
- pain with urination
- disturbed sexual function

Most of these symptoms are caused by compression of the urethra (the channel through which urine flows from the bladder) by the enlarged prostate.

Prostamol Uno prevents further enlargement of the prostate, thus reducing the pressure on bladder and improving urine stream.

Prostamol Uno does not inhibit sexual function.

If you do not feel better or feel worse, you should contact your doctor.

2. What you need to know before you take Prostamol Uno

Do not take Prostamol Uno

If you are allergic to the berries of saw palmetto extract or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Prostamol Uno.

Prostamol Uno relieves symptoms associated with prostate enlargement, it does not entail a change in size. Thus, please visit your doctor regularly.

You must tell your doctor, if

- you develop fever, seizures or notice blood in the urine
- urination is painful
- you develop urinary incontinence (low volume continuous urine leakage, so-called overflow) or you are feeling a sudden sudden urination but are unable to empty the bladder (acute urinary retention).

Children and adolescents

Use in children and adolescents under 18 years of age is not recommended.

Other medicines and Prostamol Uno

Tell your pharmacist if you are taking or have recently taken any other medicines.

Co-administration with warfarin (a blood thinner) is not recommended as the risk of bleeding may increase.

Pregnancy, breastfeeding and fertility

Prostamol Uno is not used in women, so use during pregnancy and lactation is not recommended. No data on fertility.

Driving and using machines

Prostamol Uno has no effect on the ability to drive or use machines.

3. How to take Prostamol Uno

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dosage is 1 capsule of Prostamol Uno a day, each day at the same time of the day. Swallow the capsule whole with adequate volume of liquid and after meal.

Use in children and adolescents

Use in children and adolescents under 18 years of age is not recommended.

Duration of administration

The duration of treatment shall be determined by your doctor and it depends on the course and severity of your disease.

The duration of treatment is not limited in time. Consult your doctor about the duration of treatment.

Treatment with Prostamol Uno is long-term and regular. Regular administration is necessary to achieve therapeutic effect. Improvement in symptoms can be expected in 6 weeks. It may take up to 3 months to achieve maximum therapeutic effect.

If you take more Prostamol Uno than you should

There are no reports on overdose of Prostamol Uno.

If you forget to take Prostamol Uno

Do not take a double dose to make up for a forgotten dose.

If you stop taking Prostamol Uno

If you stop using Prostamol Uno, the symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon (may affect up to 1 in 100 people)

- nausea, vomiting, diarrhea, lower abdominal pain (especially when taken on an empty stomach).

Unknown (frequency cannot be estimated based on available data)

- Allergic or hypersensitivity reactions may occur
- There may be a headache

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Prostamol Uno

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prostamol Uno contains

Each soft capsule contains 320 mg of the extract of saw palmetto berries (9–11:1).

Other ingredients are:

Succinylated gelatine, glycerol, purified water, colourings such as titanium oxide (E171), yellow iron oxide (E 172), black iron oxide (E172) and carmine lacquer (E120)

What Prostamol Uno looks like and contents of the pack

Oval soft capsules with bicolour (red/black) coating containing brown, brownish yellow or greenish brown (oily) liquid.

PVC/PVDC blister packs covered with aluminium foil.

Blister packs contain 15, 30, 60 or 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Berlin-Chemie AG

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Germany

For any information about this medicine, please contact the local representative of the

Marketing Authorisation Holder:

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This leaflet was last revised in December 2021.