



Package leaflet: Information for the user

**Prostamol® uno
320 mg, soft capsules**

Extract of saw palmetto fruits

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 use Prostamol® uno
4. Possible side effects
5. How to store Prostamol® uno
6. Contents of the pack and other information

1. What Prostamol® uno is and what it is used for

Prostamol® uno contains extract of saw palmetto fruits (*Serenoae repentis fructus extractum*), which is a herbal urological (a prostate medicine).

Prostamol uno is used for the treatment in adult men for voiding difficulties (difficulty emptying the bladder) due to benign prostatic (with non-cancerous origin) enlargement stage I and II.

Classification of stages of non-cancerous enlargement of the prostate gland (benign prostatic hyperplasia):

Stage	Name	Findings
I	Irritative stage of bladder	<ul style="list-style-type: none">- Delayed start of urination- Prolonged and intermittent urination- Weak stream of urine- Frequent urination (especially during the night)- The bladder is completely emptied by urination.
II	Residual urine stage	<ul style="list-style-type: none">- Difficulties with urination continue- The bladder is not fully emptied, with urine remaining in the bladder even after urination. The patient experiences a feeling of incomplete emptying.

The **benign prostatic hyperplasia** may have following symptoms:

- ▶ The need to urinate more often, especially during the night
- ▶ A weak or interrupted stream of urine
- ▶ “dribbling”
- ▶ Feeling of incomplete emptying of the bladder
- ▶ Pain when urinating
- ▶ Disturbances of sexual function

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

Prostamol® uno is preventing further enlargement of prostate-gland tissue.

Prostamol® uno does not disturb sexual function.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Prostamol® uno

Do not use Prostamol® uno

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Prostamol® uno:

Prostamol® uno only improves the complaints if you have an enlarged prostate gland. It does not reverse the enlargement. Therefore, please visit your doctor regularly.

You should go to a doctor particularly if:

- ▶ You have fever, spasm or blood in the urine
- ▶ You experience painful urination
- ▶ You have constant dripping of urine (overflow incontinence)
- ▶ You experience a painful urge to urinate with sudden inability to pass water (acute urinary retention)

Children and adolescents

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

Other medicines and Prostamol® uno

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

A few cases of suspected interactions with warfarin (anticoagulants) have been reported. Increased INR- values have been described.

Pregnancy, breast-feeding and fertility

Prostamol® uno is not intended for use in women, therefore use during pregnancy and breast-feeding is not recommended. No fertility data are available.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

3. How to take Prostatamol® 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 dose is 1 Prostatamol® uno soft capsule daily at the same time of each day. Swallow the soft capsule whole with sufficient liquid after a meal.

Use in children and adolescents

Prostatamol® uno is not recommended for children and adolescents under 18 years.

Length of treatment

The length of the therapy is in line with the nature, severity and course of the disease and is not limited in time. Please ask your doctor about this.

Treatment with Prostatamol® uno is long lasting and regular. Regular daily intake is particularly important for treatment to be successful. An improvement in the complaints can only be expected after about six weeks. About three months may pass before the full effectiveness is achieved.

If you take more Prostatamol® uno than you should

No cases of overdose with Prostatamol® uno are known up to now.

If you forget to take Prostatamol® uno

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

If you stop taking Prostatamol® uno

Your complaints may occur again if you stop taking Prostatamol® uno.
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, diarrhoea, abdominal pain (especially when taken on an empty stomach)

Not known: (frequency cannot be estimated from the available data):

- Allergic or hypersensitivity reactions may occur.
- Headache may occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. 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 folding box after "EXP". The expiry date refers to the last day of that month.

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 capsule contains 320 mg extract of serenoa saw palmetto fruits (9 – 11:1).
- The other ingredients are:
Succinylated gelatine, glycerol, purified water, colouring agents titanium dioxide (E 171), iron oxide yellow (E 172), iron oxide black (E 172) and carmine lacquer (E 120).

What Prostamol® uno looks like and contents of the pack

Oval soft gelatine capsule with opaque, two-coloured red/black shell with brown to yellowish- or greenish-brown (oily) liquid

Original packages with 15, 30, 60, 120, 180, 200 soft capsules
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

BERLIN-CHEMIE AG (MENARINI-GROUP)
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Germany

This leaflet was last revised in month YYYY.

Klicken Sie hier, um Text einzugeben.