

PACKAGE LEAFLET: Information for the user

FLOTRIN URO

Tablets – 5 mg

(Terazosin)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT FLOTRIN URO IS AND WHAT IT IS USED FOR

Flotrin Uro contains the active substance terazosin which belongs to a group of medicines (alpha-1-receptor blockers) that relieve the symptoms of benign prostatic hyperplasia and emptying of the bladder.

Flotrin Uro is used for the treatment of:

- concerns (clinical symptoms) and urinary symptoms associated with benign prostatic hyperplasia (BPH).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLOTTRIN URO

Do not take Flotrin Uro if:

- you are hypersensitive (allergic) to terazosin or other alfa-blockers of the group of quinazolines (e.g. prazosin, doxazosin, alfuzosin) or to any of the excipients of Flotrin Uro;
- you have previously had a transitory loss of conscience during your urination (micturition syncope).

Take special care with Flotrin Uro

- **according to the fact that Flotrin Uro affects the blood pressure**, during the treatment with the drug you should regularly visit your doctor and control the blood pressure;
- **after taking the first dose, after interruption of the treatment (for more than 2 days), or after increase of the dose, increases the risk** to cause reduction of the blood pressure. In these cases symptoms may appear, such as: weakness, vertigo and in very rare cases loss of consciousness. Therefore, in the first days, after the change of the dose or after the restart of the treatment after an interruption, prolonged standing positions and immediate change of the position should be avoided. These symptoms usually last for a short time and disappear during the continuation of the treatment. As far as the possibility of the appearance of this side effect is higher when the initial dose is higher than the recommended one, the dosage instructions should be followed carefully (see section 2 "Driving and using machines")
- **if Flotrin Uro is combined with antihypertensive drugs**, in this case the possibility of further drop in blood pressure is increased. In this situation, the doctor should determine the dose very carefully and if necessary adjust it;
- **if you have narrowing of the coronary heart vessels**, very pronounced or very rapid reduction of blood pressure that may be caused by Flotrin Uro, can aggravate your heart problems (angina pectoris). In case of deterioration, seek immediate medical attention;
- **if at the same time with Flotrin Uro you also take medicines that may affect liver metabolism** (e.g. drugs against gastrointestinal ulcers, containing cimetidine);
- **if you have the following cardiac conditions:**
 - water in the lungs (pulmonary edema) due to narrowing of the valve in the left ventricle;
 - high-output heart failure;
 - right ventricular muscle weakness (right ventricular insufficiency) caused by pulmonary

embolism or pericardial effusion;

- left ventricular muscle weakness (left ventricular insufficiency with low filling pressure);
- **if you have impaired liver function:** ask your doctor for the dose if you have mild liver function impairment because Flotrin Uro should be dosed with special care in these cases. If you have severe liver function impairment, you should not use Flotrin Uro.

Flotrin Uro **should not be** used if you have prostate enlargement and at the same time you have congestion in the upper parts of the urinary tract, chronic urinary tract infection, bladder stones, incontinence, almost complete urine deficiency or advanced renal failure.

If you will undergo eye surgery because of a cataract, you should notify the appropriate doctor that you use this medicine or have used it before. This is necessary because in some patients, the simultaneous or previous intake of Flotrin Uro has caused difficulties during surgery (e.g. inadequate pupil enlargement, iris relaxation during the intervention). The doctor will take the necessary measures for the treatment and technique used during surgery. Ask your doctor if because of the cataract surgery you should temporarily stop or postpone your treatment. If you are not sure, please talk to your doctor again.

Children

Flotrin Uro should not be used in children, because until now there is not enough experience of the overall effect on this age group.

Elderly and patients with impaired renal function

Consult your doctor because Flotrin Uro should be dosed with special care in this group of patients.

Taking other medicines

Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

The blood pressure reduction that causes Flotrin Uro can be enhanced by other antihypertensive drugs (e.g. ACE-inhibitors, beta-blockers, calcium antagonists, diuretics).

Do not take Flotrin Uro **in combination** with other alpha-blockers of the quinazoline group (e.g. doxazosin, prazosin, alfuzosin).

Flotrin Uro and the so-called 5-phosphodiesterase inhibitors (e.g. sildenafil, tadalafil and vardenafil): in some patients who take alpha-blockers for treating high blood pressure or prostate enlargement, vertigo or numbness may appear.

These may come as a result of a rapid drop in pressure when sitting down or getting up quickly. In certain patients these concerns have arisen when they have taken at the same time medicines against erectile dysfunction (impotence) and alpha-blockers. To avoid the onset of these symptoms, if you are using medicines against erectile dysfunction, you should be stabilized with an appropriate daily dose of alpha-blockers.

Taking Flotrin Uro with food and drinks

No special measures are needed.

Driving and using machines

Flotrin Uro's influence on blood pressure requires regular medical examinations. Because the response to the reaction is individual and different, it can happen to affect the ability to drive the vehicle, use machinery or to work without having a secure foothold. This is especially true at the beginning of the therapy, when the dose increases or when the preparation changes as well as when it is used with alcohol.

You should not ride on a motorcycle or perform hazardous work (e.g. climb on a roof or pier) within the first 12 hours after taking the first tablet, at the beginning of the treatment, or after a dose increase, because at this time there may be a decrease in blood pressure. If this happens, you may feel disturbances such as dizziness, numbness or feeling of weakness.

Important information for some of the excipients of Flotrin Uro

This medicine contains lactose. Please take Flotrin Uro only after you have talked to your doctor if you know you are suffering from intolerance to certain sugars.

3. HOW TO TAKE FLOTTRIN URO

Always take Flotrin Uro exactly as your doctor has told you. If you are not sure, contact your doctor or pharmacist.

Please follow the instructions for use, otherwise this medicine will not have the expected effect.

In principle, treatment with terazosin should start with the lowest dose (1 mg terazosin) and slowly increase to the required individual dose.

Once you have done this, you should continue to take 1 tablet of Flotrin Uro 5 mg daily.

Taking more than 2 tablets of Flotrin Uro per day does not lead to further improvement of the symptoms.

After the beginning of the treatment, the shortest time to see the improvement of the symptoms is after 2 weeks.

If at the same time you take antihypertensive drugs, the Flotrin Uro dosage should be taken very carefully.

Consult the dose of Flotrin Uro or that of antihypertensive drugs with your doctor (see section 2 "Taking other medicines").

In elderly people or patients with liver or kidney function disorders, dosage requires special care (see section 2 "Take special care with Flotrin Uro").

Method of administration

Take the first tablet of a given dose at dinner before bedtime. You can take the other tablets of the same dose in the morning or at dinner time.

Please take the tablet without breaking or chewing it, with enough liquid (preferably one glass of water). You can take the tablet independently of the meals.

Duration of administration

The duration of use will be determined by your doctor. Treatment with terazosin is a long-term treatment. Stop the therapy only with the doctor's instructions. If you have stopped the treatment for more than 2 days, Flotrin Uro dosing should be done like at the start of the therapy and the dose should be increased slowly. Restart with 1 mg terazosin at dinner. Please talk to your doctor if you have the impression that the effect of Flotrin Uro is too strong or too weak or if any side effects occur.

If you take more Flotrin Uro than you should

You may have a drop in blood pressure till a transitional loss of conscience.

Depending on the dose of terazosin taken, life-threatening situations may occur, such as cardiovascular insufficiency. Please inform the doctor immediately in case of overdose so that he or she will decide for further processing. If there are concerns such as: numbness, dizziness, feeling of weakness or loss of consciousness, you should stay in lying position on the back, with raised legs (lower head) to normalize blood pressure and heartbeats. If the pressure drop is extreme, the doctor may use the appropriate medication. Dialysis is of no value because terazosin is not eliminated by dialysis.

If you forget to take Flotrin Uro

Do not take a double dose, but continue with the dose you have been prescribed.

If you stop taking Flotrin Uro

Treatment with medicines for benign prostate hyperplasia is usually a long-term treatment. If you stop taking Flotrin Uro, for example when side effects occur, consult your doctor first. If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flotrin Uro can cause side effects, although not everybody gets them.

For the assessment of side effects, the following frequency indicators are used:

Very common: more than 1 in 10 patients
Common: less than 1 in 10, but more than 1 in 100 patients
Uncommon: less than 1 in 100, but more than 1 in 1,000 patients
Rare: less than 1 in 1,000, but more than 1 in 10,000 patients
Very rare: less than 1 in 10,000 patients
Unknown: frequency cannot be estimated from the available data

Potential side effects

Like other similar drugs (alpha-blockers), terazosin can cause transient loss of conscience. These appear mostly within 30 to 90 minutes after taking the tablet. As a reason, it is considered mainly the reduction of blood pressure when the position is changed. Partially, it can also be due to increased heart rate (120 - 160 / min.).

Effects on blood and lymphatic system

Very rare: decrease in the number of blood platelets

Effects on nervous system

Common: disturbances of perception and mood disorders

Effects on eye

Uncommon: eye disturbances (misperception of colors / blurred vision)

Effects on heart

Common: decrease of blood pressure when the position is changed (orthostatic disorder), chest pain, palpitations

Uncommon: increased frequency of heartbeats

Very rare: atrial fibrillation

Effects on respiratory, thoracic and mediastinal routes

Common: shortness of breath, "runny nose", rhinitis, nasal bleeding

Effects on gastrointestinal tract

Common: nausea

Uncommon: constipation, diarrhea, vomiting

Effects on skin and subcutaneous tissue

Uncommon: itching, unspecific skin reactions, e.g. hives

Effects on kidneys and urinary tract

Uncommon: concerns about emptying the bladder

Effects on genitals

Common: impotence, abnormal ejaculation (e.g. blood in the sperm)

Uncommon: prolonged, painful erection of the penis, without sexual cause (priapism), decreased sexual desire (libido).

General disorders and administration site conditions:

Common: dizziness, numbness, fatigue, feeling of weakness

Uncommon: headache, swelling (edema), weight gain, transitory loss of conscience

Very rare: severe hypersensitivity reactions (anaphylactic reactions)

There have been reports of hernia.

Others:

The following side effects, which do not have a causal relationship with terazosin, have been observed in clinical studies or aftermarket launch: fever, abdominal pain, neck pain, back and shoulders pain, enlargement of the blood vessels, heart rhythm disturbances, dry mouth, digestive problems, flatulence, gout, joint pain, inflammation of the limbs, muscle pain, bruising, anxiety, depression, insomnia, bronchitis, flu-like symptoms, pharyngitis, sinusitis, common cold symptoms, skin rash, cough, sweating, connective tissue inflammation, noise in the ear, impotence, frequent urination, bladder infection, urinary incontinence.

Clinical studies indicate that there may be blood thinning caused by the use of terazosin, as a result, blood cells may appear to be reduced in number.

If you need to perform cataract surgery in the eye, and take or have taken Flotrin Uro earlier, difficulties may occur during the procedure (see "Take special care with Flotrin Uro").

Measures that should be taken

The most frequent side effect of terazosin is the reduction of blood pressure, which may appear as dizziness, numbness or feeling of weakness.

If you notice these effects, sit down immediately or lie down as long as your concern is over. Tell your doctor about this event, so that it can be reflected in the dose you take.

Another possible side effect of terazosin is prolonged, painful erection of the penis, without sexual cause. If this effect appears, ask your doctor straight away, because without medical treatment, erectile dysfunction may be prolonged.

Please inform your doctor or pharmacist if any side effects disturb you or if you notice any side effects not mentioned in this leaflet.

5. HOW TO STORE FLOTTRIN URO

Do not store above 25°C!

Store in the original packaging to protect the tablets from light and humidity!

Keep out of the sight and reach of children.

Do not use Flotrin Uro after the expiry date which is stated on the package and in the blister.

6. OTHER INFORMATION

What Flotrin Uro contains:

The active substance is terazosin hydrochloride dihydrate.

Each tablet contains 5.935 mg terazosin hydrochloride dihydrate equivalent to 5 mg of terazosin.

The excipients are: lactose monohydrate, maize starch, pregelatinised starch, talc, magnesium stearate, iron oxide red.

Content of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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