

Uniprost®

1. What this product is and what it is used for

Uniprost® belongs to the group known as vasodilators. These substances cause the blood vessel to widen, which reduces the blood pressure.

UNIPROST® can also reduce tension in the muscle tissues of the prostate and the urinary tract.

Uniprost® is used to treat:

- high blood pressure;
- symptoms of an enlarged prostate.

2. What you need to know before you use this product

Do not take

- If you are allergic (hypersensitive) to doxazosin, other medicines from the same group (known as quinazolines, such as e.g. prazosin and terazosin) or any of the other ingredients of Uniprost®.
- If you have a history of a condition known as 'orthostatic hypotension' which is a form of low blood pressure that causes you to feel dizzy or lightheaded when you stand up from sitting or lying down.
- If you have an enlarged prostate gland with one of the following: any kind of congestion or blockage in your urinary tract, a longstanding infection of the urinary tract or you have bladder stones.
- If you are breastfeeding.
- If you have an enlarged prostate gland (benign prostatic hyperplasia) and have low blood pressure.
- If you have overflow incontinence (you do not feel the urge to urinate), or anuria (your body is not producing any urine) with or without kidney problems.

Tell your doctor before you start to take this medicine if you:

Suffer from serious heart problems such as e.g. severely reduced cardiac function or a restrictive and painful sensation in the chest (angina pectoris);

- Are on a strict low salt diet;
- Are using diuretics;
- Have kidney or liver problems.

If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Uniprost®. This is because UNIPROST® may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Using other medicines

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

- Some patients who take alpha blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or lightheadedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with alpha blockers. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha blocker before you start drugs for erectile dysfunction.
- Uniprost® may lower your blood pressure even more if you are already taking other medicines to treat high blood pressure such as terazosin and prazosin.
- Nitrates (medicines for heart problems) such as nitroglycerine and isosorbide nitrate: these can exacerbate the hypotensive effect.
- Certain painkillers for rheumatism (known as non-steroidal anti-inflammatory drugs) such as naproxen, ibuprofen or any other anti-inflammatory painkiller: these can reduce the hypotensive effect.
- Medications that could also possibly affect the liver metabolism. e.g. cimetidine (a medicine for stomach problems).

Pregnancy and breast-feeding

If you are pregnant or think you might be pregnant you should contact your doctor before taking Uniprost®. Uniprost® should only be used during pregnancy if your doctor decides that the benefits for the mother outweigh the possible risk for the foetus.

Do not breast feed while taking Uniprost®.

Driving and using machines

Uniprost® can sometimes cause dizziness or fainting. In such an event, you should exercise care during activities that require attentiveness, such as driving, operating machinery and working at heights. If you are unsure whether Uniprost® is having a negative effect on your ability to drive, discuss this with your doctor.

3. How to use this product.

Always take Uniprost® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

HIGH BLOOD PRESSURE: The initial dose is 1mg daily (= 24 hours) in a single dose. After 1 to 2 weeks, the dose is generally increased to 2mg in a single daily dose (= 24 hours). This dose is also retained for 1 to 2 weeks. If necessary, the dosage can be further increased to 4, 8 or 16mg per day, until the desired reduction in blood pressure is achieved. The maximum daily dose is 16mg. An initial dose should preferably be taken before going to bed; this means that any dizziness you may experience is less of a problem.

ENLARGED PROSTATE: The initial dose is 1mg daily (= 24 hours) in a single dose. After this the usual dose is 2mg or 4mg daily. In some circumstances this may be increased to a maximum of 8mg daily. The tablets should be taken as a single dose each day (= 24 hours). The tablets must be taken with plenty of water.

If you take more Uniprost® than you should

If you have taken more than the prescribed dose, you should consult your doctor and/or pharmacist immediately. If you feel extremely dizzy or think you might faint, you should lie down immediately with your head down.

If you forget to take Uniprost®

If you have forgotten to take a tablet, then skip it and take the next tablet at the usual time. You should check with your doctor or pharmacist if you are unsure. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Uniprost®

If you suddenly stop taking Uniprost®, the complaints you suffered prior to the start of treatment may recur. It is therefore better not to stop taking this medication suddenly. Your doctor will decrease the dosage gradually. You should always check with your doctor or pharmacist if you are unsure.

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

4. Possible side effects

Like all medicines, Doxazosin can cause side effects, although not everybody gets them. Some side effects could be serious:

If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions such as wheezing, shortness of breath, extreme dizziness or collapse, swelling of the face or throat, or a serious skin rash with red spots or blisters.
- Chest pain, increased or irregular heartbeat, heart attack or stroke.

- Yellowing of the skin or whites of the eyes, caused by liver problems.
- Unusual bruising or bleeding caused by low blood platelets.

These side effects are uncommon (affects 1 to 10 users in 1,000) or rare (affects 1 to 10 users in 10,000)

Other side effects:

Very common (affects more than 1 users in 10)

- Dizziness, headache.

Common (affects 1 to 10 users in 100):

- Respiratory tract infection, inflammation of the air passages within the lungs, cough, shortage of breath, nasal stuffiness and/or runny nose.
- Urinary tract infection, urinary incontinence (inability to control passing urine).
- Loss of appetite.
- Anxiety, sleeplessness (insomnia), nervousness.
- Dizziness, tingling or numbness of the hands and feet (paraesthesia), sleepiness (somnolence).
- Feeling of dizziness or "spinning" (vertigo).
- Feeling or sensation of irregular heartbeat (palpitation), increased heart rate.
- Low blood pressure and low blood pressure as a result of getting up from a sitting or lying position (postural hypotension).
- Abdominal pain, indigestion, dry mouth, feeling sick (nausea), diarrhoea itching (pruritus).- Back pain, muscle pain (myalgia).
- Inflammation of the bladder (cystitis).
- Feeling of weakness (asthenia), chest pain, influenza-like symptoms.
- Swelling of the ankles, feet or fingers (peripheral oedema), feeling tired (fatigue), malaise.

Uncommon (affects 1 to 10 users in 1,000):

- Allergic drug reaction.
- Gout, increased appetite.
- Agitation, depression.
- Stroke, reduced sense of touch or sensation, fainting.
- Ringing or noise in the ears (tinnitus).
- Chest pain (angina pectoris), heart attack (myocardial infarction), irregular heartbeat.
- Flushing.
- Nosebleed, cough.
- Constipation, flatulence, vomiting (being sick), inflammation of the gastrointestinal tract.
- Abnormal liver function test.
- Skin rash, hair loss (alopecia), rash caused by bleeding under the skin (purpura)-
- Joint pain, muscle cramps, muscle weakness.
- Painful or difficult urination, presence of red blood cells in the urine (hematuria), urinary incontinence (inability to control passing urine).
- Difficulty to develop an erection (impotence).
- Pain, swelling of the face.
- Weight increase.

Very Rare (affects less than 1 user in 10,000):

- Reduced numbers of blood platelets.
- Reduced number of white and red blood cells.
- Blurred vision.
- Reduced heart rate.
- Bronchial spasm.
- Blocked flow of bile (cholestasis), inflammation of the liver (hepatitis).
- Yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice).

- Abnormal liver function tests.
- Increased blood levels of urea and creatin.
- Obstruction to the normal flow of bile (cholestasis) which may cause jaundice (yellowing of the skin or whites of the eyes).
- Inflammation of the liver (hepatitis).
- Hives (urticaria).
- Disorder in passing urine, needing to pass urine at night, increased volume of urine passed.
- Temporary enlargement of the breasts (gynaecomastia), painful persistent erection.

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

- Eye problems may occur during eye surgery for cataract (cloudiness of the lens of the eye). See section "Take special care with Doxazosin".

- Taste disturbances.

- Little or no semen ejaculated at sexual climax, cloudy urine following sexual climax (retrograde ejaculation).

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.

5. How to store this product

- Store at temperature not exceeding 30 °C.
- Keep out of the reach of children.
- Do not use Uniprost® Tablets after the expiry date (EXP) which is stated on the box and blister. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

a. What this product contains

The active substance is: Doxazosin. Each cross scored tablets contains 4 mg Doxazosin (as mesylate).

The other ingredients are: Lactose monohydrate, Povidone, Polysorbate 80, Magnesium stearate, Microcrystalline cellulose, Colloidal silicon dioxide, Sodium starch glycolate, Isopropyl alcohol

b. What this product looks like and contents of the pack

Uniprost® Tablets are white round biconvex uncoated tablets. Uniprost® Tablets is presented in a carton box containing 20 tablets in blisters along with a patient information leaflet.

c. Marketing Authorization Holder and Manufacturer

BATTERJEE PHARMA

Street No.: 401, Road No.: 403,

Industrial Area-Phase-IV,

P.O. Box: 10667,

Jeddah-21443,

Kingdom of Saudi Arabia.

d. This leaflet was last revised in {MM/YYYY}

05/2014