

AVELOSIN PROLONGED RELEASE TABLET

Tamsulosin Hydrochloride (0.4mg)

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What AVELOSIN is used for

AVELOSIN is used to treat the symptoms associated with benign prostatic hyperplasia (BPH) which is enlargement of the prostate gland.

These symptoms include difficulty in starting to pass water, frequent trips to the toilet to pass water, a feeling of not completely emptying the bladder and having to get up several times in the night to pass water.

How AVELOSIN works

The active ingredient in AVELOSIN is tamsulosin hydrochloride. It acts by relaxing the muscles in the prostate and urethra (the tube that carries urine to the outside), and lets urine pass more readily through the urethra and aids urination.

In the prostate gland, bladder and urethra there are specialized cells containing alpha1A-receptors that cause the muscles in the urethra to tighten. AVELOSIN is an alpha1A-adrenoceptor blocker, which reduces the action of these specialized cells and relaxes the muscles making it easier to pass water.

Before you take AVELOSIN

- When you must not take it

Do not use AVELOSIN if you:

- are allergic (hypersensitive) to tamsulosin or any of the other ingredients of this medicine (see **Product Description**).
- have a severe liver condition,
- have ever fainted or felt dizzy when suddenly sitting or standing up. Dizziness can sometimes occur when taking AVELOSIN, particularly if you are also taking other alpha-blockers. If you do feel weak or dizzy make sure you sit or lie down straight away until the symptoms have disappeared.

Do not give this medicine to children or adolescents under 18 years because it does not work in this population.

AVELOSIN is not indicated for use in women.

In men, abnormal ejaculation has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

- Before you start to take it

Take special care with AVELOSIN and talk to your doctor:

- if you have kidney problems,
- if you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract)

Please inform your eye specialist that you have previously used, are using or are planning to use tamsulosin hydrochloride. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used.

Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens.

- Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because AVELOSIN can affect the way that some other medicines work and some other medicines can affect the way that AVELOSIN works.

In particular tell your doctor or pharmacist if you are taking:

- Medicines to lower your blood pressure such as verapamil and diltiazem
- Medicines to treat a fungal infection such as ketoconazole or itraconazole

- Other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin
- Erythromycin, an antibiotic used to treat infections
- Diclofenac
- Warfarin

How to take AVELOSIN

- How much to take

For adults and the elderly, the dose is one tablet each day.

Your doctor may want to examine you from time to time whilst you are taking this medicine.

- When to take it

Use as directed by your doctor or pharmacist.

It can be taken with or without food.

Swallow the tablet whole. Do not crunch or chew.

- How long to take it

Continue taking AVELOSIN for as long as your doctor recommends.

- If you forget to take it

You may take your tablet later the same day if you have forgotten to take it earlier. If you have missed a day, just continue to take your daily tablet from the next day.

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

- If you take too much (overdose)

If you have taken too many tablets, contact your doctor immediately or go to the nearest hospital casualty department taking any remaining medication and this patient information leaflet with you.

While you are taking AVELOSIN

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

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- Things to be careful of

Please inform your doctor that you are on AVELOSIN before any operation or dental procedure as there is a potential that your medicine may interfere with the effects of the anaesthetic.

Driving and using machines:

There is no evidence that AVELOSIN affects the ability to drive or to operate machinery or equipment.

However, you should bear in mind that dizziness can occur, in which case you should not undertake activities that require attentiveness.

Side Effects

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

Rare (affects less than 1 in 1000 people):

- Swelling of the face, throat or tongue with breathing problems linked to allergy

Very rare (affects less than 1 in 10,000 people):

- Persistent painful erection usually unrelated to sexual activity.
- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome).
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).

The following side effects have also been reported:

Common (affects less than 1 in 10 people):

- Dizziness
- Ejaculation disorder

Uncommon (affects less than 1 in 100 people)

- Weakness
- Headache
- Runny or blocked nose
- Dizziness as you sit or stand up
- Palpitations (rapid or irregular heart beat)
- Gastro-intestinal symptoms such as nausea and vomiting (feeling or

being sick), diarrhoea or constipation

- Hypersensitivity reactions such as rash, itching, redness, local swelling and breathing problems

Rare (affects less than 1 in 1000 people)

- Fainting

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

- Blurred vision
- Impaired vision
- Nose bleeds (epistaxis)
- Serious skin rashes (erythema multiform, dermatitis exfoliative)

As with other medicines of this type, drowsiness, blurred vision, dry mouth or swelling of the hands and feet can occur.

Tell your doctor or pharmacist if any of the above symptoms become troublesome or last longer than a few days, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AVELOSIN

- Storage

Do not store above 30 °C.

- Disposal

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.

Product Description

- What it looks like

Yellow, film coated, round, biconvex tablet engraved "04" on one side.

- Ingredients

- Active ingredient:
Tamsulosin hydrochloride

- Inactive ingredients:
Tablet core:

Macrogol 7 000 000; cellulose, microcrystalline type 200 (E460); silica, colloidal anhydrous type 200 (E551), magnesium stearate (E470b)

Film-coating:

Hypromellose HPMC 2910 (E464), titanium dioxide (E171), macrogol 8000, iron oxide yellow (E172)

- MAL number:

MAL*****

Manufacturer

Adamed Pharma S.A.
ul. Marszałka Józefa Piłsudskiego 5,
95-200, Pabianice, Poland.

Product Registration Holder

Abio Marketing Sdn Bhd
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