

ANDROZ TABLET

Sildenafil Citrate (50 mg, 100 mg)

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What Androz is used for

Androz is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

In order for Androz to be effective, sexual stimulation is required.

How Androz works

Sildenafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Sildenafil is an oral therapy for erectile dysfunction. In the natural setting, i.e. with sexual stimulation, sildenafil restores impaired erectile function by increasing blood flow to the penis. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited.

Sildenafil will only help you to get an erection if you are sexually stimulated.

Before you use Androz

- When you must not use it

Androz is contraindicated in patients with a known hypersensitivity to any component of the tablet.

Androz was shown to potentiate the hypotensive effects of acute and chronic nitrates. Do not take Androz if you are using nitric oxide donors, organic nitrates or organic nitrites in any form either regularly or intermittently.

Pregnancy and lactation

Androz is not indicated for use by women. Thus, do not use this medicine if you are a woman.

- Before you start use it

Talk to your doctor, pharmacist or nurse before taking Androz if any of the following applies to you:

- If you have sickle cell anaemia (an abnormality of red blood cells), leukemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you have an anatomical deformation of the penis (such as angulation, cavernosal fibrosis or peyronie's disease).
- If you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex.
- Caution should be advised when Androz taken with other blood pressure lowering agent, as the co administration may lead to symptomatic hypotension.
- If you currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking this medicine and contact your doctor immediately.
- If you experience sudden decrease or loss of hearing, stop taking this medicine and contact your doctor immediately.
- You should not use this medicine combine with any other oral or local treatments for erectile dysfunction.
- You should not take Androz if you do not have erectile dysfunction.
- You should not take Androz if you are a woman.

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Children and adolescents

This medicine should not be given to individuals under the age of 18.

- Taking other medicines

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

Androz tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor,

pharmacist or nurse that you have taken this medicine and when you did. Do not take this medicine with other medicines unless your doctor tells you that you can.

You should not take this medicine if you are taking medicines called nitrates (known as nitric oxide donors, organic nitrates, or organic nitrites) or PDE5 inhibitors, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of this medicine.

Some patients who take alphablocker therapy may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Androz with alpha-blockers. You should be on a regular daily dose of your alpha-blocker before you start this medicine. Your doctor may start you on a lower dose of Androz.

How to use Androz

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended starting dose is 50 mg.

Based on effectiveness and toleration, the dose may be increased to a maximum recommended dose of 100 mg or decreased to 25 mg.

The maximum recommended dosing frequency is once per day.

You should take this medicine about one hour before you plan to have sex.

If you feel that the effect of this medicine is too strong or too weak, please talk to your doctor or pharmacist.

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If you have a liver or kidney disorder or are elderly, you should consult your doctor. Your doctor tells you that how many tablets you need to take.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Androz for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Always take your medicine as recommended by your doctor. You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Androz.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Androz to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Doses above 100 mg do not increase the efficacy.
- Androz should not be used in individual below 18 years of age.

- Always follow your doctor's instructions carefully if you want to stop medication.

Driving and using machines

This medicine can cause dizziness and altered vision can affect vision. You should be aware of how you react to this medicine before you drive or use machinery.

Side effects

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

The side effects reported in association with the use of this medicine are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Androz and seek medical help immediately:

- An allergic reaction (this occurs rarely) or serious skin reactions.
- Headache and dizziness.
- Chest pains (this occurs uncommonly).
- Sudden decrease or loss of hearing.
- Sudden decrease or loss of vision.
- Nasal congestion or stuffy nose.
- Indigestion.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Androz

- Storage

- Store in the original package.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date printed on the pack.
- Keep out of the reach and sight of children.
- Store below 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

Androz 50 mg tablets are blue, round biconvex, film coated tablets, debossed with '8' bisect '7' on one side and plain on other side.

Androz 100 mg tablets are blue, round biconvex, film coated tablets, debossed with '8' bisect '8' on one side and plain on other side.

Ingredients

Active ingredient

- Sildenafil citrate.

Inactive ingredients

- Cellulose, microcrystalline.
- Croscarmellose sodium.
- Calcium hydrogen phosphate anhydrous.
- Sodium stearyl fumarate.
- Hypromellose.
- Titanium dioxide.
- Triacetin.
- Lake of indigo carmine.

- MAL number(s):

Androz 50 mg Tablets
MALXXXXXXXXXX

Androz 100 mg Tablets
MALXXXXXXXXXX

Manufacturer

Torrent Pharmaceuticals LTD.
Indrad 382 721, District: Mehsana,
India.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn. Bhd.
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
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