Package leaflet: Information for the User Aronix® 50 mg Film-Coated Tablets

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 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 pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.
- If you have taken Aronix as directed and were NOT able to get or keep an erection hard enough for satisfactory sex, you should talk to your pharmacist or doctor.

• have a problem with one of the valves in

have a disease in which the heart muscle

becomes inflamed and does not work as

your heart (valvular heart disease)

well as it should (cardiomyopathy)

have an irregular heart beat (arrhythmia)

have had a surgery to improve blood flow

to your heart, or you have high blood

have ever had an erection that lasted more

than 4 hours even without any physical or

psychological stimulation; (called priapism);

multiple myeloma (cancer of bone marrow)

or have any condition which can cause

priapism. Conditions which can cause

priapism include sickle cell anaemia

leukaemia (cancer of blood cells), or

take any other medicines listed in this

leaflet. Please refer to section 2 'Other

have a stomach ulcer, or a bleeding

moderate liver disease, or severe kidney

Aronix may not be suitable for you. Ask

your pharmacist or doctor about a 25 mg

This medicine should not be given to children

taking, have recently taken or might take any

affected by Aronix or they may affect how well

Nitrate medicines: Do NOT take Aronix if

you are taking nitrate medicines (such as

glyceryl trinitrate, isosorbide mononitrate,

isosorbide dinitrate) or nitric oxide donors

(such as amyl nitrite ("poppers"),

nicorandil or sodium nitroprusside).

pain (angina pectoris), or heart failure.

Do not take Aronix if you are taking a

of a group called guanylate cyclase

lungs due to blood clots).

Aronix if you are taking:

works such as:

HIV infections

Aronix with food and drink

the medicine works.

Aronix can be taken with or without food.

meal, it may take a little longer to start

When this medicine is taken after a high-fat

working. Do not take Aronix with grapefruit or

grapefruit juice, because this can affect how

Drinking excessive alcohol can temporarily

are advised not to drink large amounts of

alcohol before sexual activity.

Driving and using machines

the ingredients of Aronix

before taking this medicine.

Other important information

provide you with further advice.

reduce your ability to get an erection. To get

Pregnancy, breastfeeding and fertility

This medicine should not be used by women.

Aronix can cause dizziness and can affect

your vision. Do not drive or use machines if

you suffer from these side effects after taking

Important information about some of

If you have been told by your doctor that you

have intolerance to some sugars, such as

lactose, speak to your pharmacist or doctor

You can improve your erectile function by

exercising regularly, reducing stress, giving up

smoking and avoiding excessive alcohol use.

If you are feeling depressed or anxious, talk to

your pharmacist or doctor, who will be able to

making lifestyle changes; these include

the maximum benefit from your medicine, you

for HIV infection.

These are often used for the relief of chest

lead to a dangerous fall in blood pressure.

medicine called riociguat (or other medicines

stimulators), used to treat pulmonary arterial

hypertension (i.e. high blood pressure in the

hypertension (i.e. high blood pressure in the

lungs) and chronic thromboembolic pulmonary

In addition, do not take Aronix if you are taking

a medicine called ritonavir, for the treatment

Tell your pharmacist or doctor before using

doxazosin or tamsulosin, which are

due to an enlarged prostate (benign

any other treatment for erectile dysfunction.

medicines used to treat urinary problems

prostatic hyperplasia) or occasionally high

blood pressure, as Aronix may not be

medicines that may affect the way Aronix

the heartburn treatment cimetidine

- medicines to treat fungal infections

Aronix may not be suitable for you. Ask

your pharmacist or doctor about a 25 mg

tablet which may be more suitable for you.

called itraconazole or ketoconazole,

and an antibiotic called erythromycin.

protease inhibitors (saquinavir) to treat

Using Aronix with any of these medicines may

other medicines. Some medicines may be

and adolescents under the age of 18 years.

Tell your pharmacist or doctor if you are

tablet which may be more suitable for you.

disorder (such as haemophilia)

have previously diagnosed mild to

medicines and Aronix'

Children and adolescents

Other medicines and Aronix

problems

(an abnormality of red blood cells),

pressure which is now under control

- What is in this leaflet
- 1. What Aronix is and what it is used for 2. What you need to know before you take •
- Aronix
- 3. How to take Aronix
- Possible side effects

information

- 5. How to store Aronix 6. Contents of the pack and other

1. What Aronix is and what it is used for

Aronix is a treatment for adult men (aged 18 years and older) with erectile dysfunction (also known as impotence). This is when a man cannot get or keep an erection hard enough for satisfactory sexual activity.

Erections depend on many things, including proper blood flow to the penis. If blood cannot flow adequately to the penis, it can cause erectile dysfunction. Erectile dysfunction is a

differently. Some men cannot get an erection, other men can get an erection but it may not be hard enough for sex, or they may lose their

erection before or during sex. Aronix contains the active ingredient sildenafil. It belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by relaxing the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited and causing an erection. Aronix will only help you to get an erection if you are sexually excited (stimulated).

2. What you need to know before you take Aronix

Do not take Aronix if you:

- do not have an erection problem, as this medicine will not provide any benefit to you take any medicines called nitrates or
- nitric oxide donors, (such as glyceryl trinitrate, isosorbide mononitrate. isosorbide dinitrate for the relief of chest pain, or heart failure or amyl nitrite also known as "poppers", nicorandil or sodium nitroprusside), as the combination may lead to a dangerous fall in blood pressure
- are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6)
- take **riociguat** or other medicines of a group called guanylate cyclase stimulators. This medicine is used to treat pulmonary arterial hypertension (i.e. high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e. high blood pressure in the lungs due to blood clots)
- take ritonavir for the treatment of HIV infection
- have been advised by your doctor to avoid
 alpha-blockers such as alfuzosin, sexual activity because of a problem with vour heart or blood vessels, such as a recent heart attack or stroke (within the last 6 months), unstable angina or severe cardiac failure
- have ever had loss of vision because of damage to the optic nerve [such as non-arteritic anterior ischaemic optic neuropathy (NAION)] or have an inherited eye disease (such as retinitis pigmentosa)
- have low blood pressure (which can cause symptoms such as tiredness, dizziness, lightheadedness, feeling sick, clammy skin, depression, loss of consciousness, or blurry vision) or high blood pressure that is not controlled
- have a severe liver problem
- have any disease or deformity of your penis (such as Peyronie's Disease)
- are a woman are under 18 years of age.

Warnings and precautions Sexual activity can put extra strain on your

If you have a heart problem or think you might have a heart problem you should tell your pharmacist

It is important to have a check-up with your doctor as soon as possible within the first 6 months of using Aronix to ensure that your erection problems are not caused by

Even if you feel healthy, your erection problems may be linked to other serious health conditions.

another serious health condition.

Erectile dysfunction may be an early sign of:

- heart and blood vessel problems
- diabetes
- high blood pressure high cholesterol

You should discuss your symptoms and these conditions with your doctor if you have not already done so.

Before taking Aronix, in order to ensure this medicine is suitable for you and that you are fit enough to have sex, tell your doctor if you:

 get very breathless or feel any pain in the chest with light or moderate activity (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex

- if you are not sure.
- swallow the table whole with water

work varies from person to person, but it

sexual activity no rush. If you are not successful the first couple of attempts before you are able to

Talk to your doctor if you have taken Aronix as directed and are still not able to get and keep an erection.

If you take more Aronix than you should

If you take more tablets than recommended, contact your pharmacist or doctor immediately. Taking more than the recommended dose may result in an increase

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

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

moderate and of a short duration.

STOP TAKING Aronix and seek medical attention IMMEDIATELY if you experience any of the following SERIOUS side effects:

- chest pains: this occurs uncommonly. If this occurs before, during or after intercourse get in a semi-sitting position
- a persistent and sometimes painful this occurs rarely
- a sudden decrease or loss of vision: this occurs rarely an allergic reaction: this occurs
- uncommonly. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips
- Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Syndrome (TEN): this occurs rarely. Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever
- seizures or fits: this occurs rarely

Very common (may affect more than 1 in 10 people): headache

Common (may affect up to 1 in 10 people):

- a sudden feeling of heat in your upper
- disturbance

1 in 100 people):

- vomiting, upper abdominal pain, gastro-oesophageal reflux disease (also known as acid reflux with symptoms including heartburn)
- skin rash, pain in the arms or legs,
- eye irritation, bloodshot eyes/red eyes, eye pain, seeing flashes of light, visual
- brightness, light sensitivity, watery eyes
- low blood pressure (symptoms include dizziness, fainting, blurred vision, nausea
- muscle pain, feeling sleepy, reduced sense
- dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose and stuffy nose)

the nose, feeling irritable and sudden

- stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of
- feeling of tightening of the throat, numb
- vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of your vision, seeing halos around lights, dilation of the pupil of the eye,
- discolouration of the white of the eye

3. How to take Aronix

Always take Aronix exactly as described in this leaflet or as your pharmacist or doctor has told you. Check with your pharmacist or doctor

- take one tablet, as needed, approximately
- 1 hour before sexual activity
- do not take more than one tablet a day

You will not get an erection just by taking Aronix. This medicine will only help you get an erection if you are sexually aroused. You and your partner should engage in foreplay just as you would if you were not taking a medicine for erectile dysfunction. The amount of time this medicine takes to

normally takes between 30 to 60 minutes to work. You may take it up to 4 hours before

Remember to relax and be patient. There is time, try to have sex again, but remember you can only take 1 tablet a day. For most men, Aronix will work the first or second time they try it. If it has been some time since you were lable to get or keep an erection, it may take a achieve an erection. If you feel the effect of Aronix is too strong or too weak, talk to your pharmacist or doctor.

in side effects and/or their severity.

4. Possible side effects

These side effects are usually mild to

- and try to relax. Do NOT use nitrates to treat your chest pain
- erection lasting longer than 4 hours:
- serious skin reactions such as

Other side effects that have been reported:

- nausea, indigestion, stuffy nose, dizziness • facial flushing, hot flush (symptoms include
- colour tinge to vision, blurred vision, visual

Uncommon (may affect up to

- nosebleed, feeling hot, feeling tired
- pounding heartbeat, rapid heartbeat high blood pressure
- and tiredness)
- of touch, vertigo, ringing in the ears (symptoms include runny nose, sneezing
- presence of blood in urine
- Rare (may affect up to 1 in 1,000 people): fainting, dry nose, swelling of the inside of
- decrease or loss of hearing
- the brain mouth
- bleeding at the back of the eye, double the eye or eyelid, small particles or spots in
- penile bleeding, presence of blood in

Cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, most, but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to this medicine. Reporting of side effects If you get any side effects, talk to your doctor

or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aronix

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister 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

What Aronix contains The active substance is sildenafil citrate. Each film-coated tablet contains 50 mg

information

sildenafil (as citrate). The other ingredients are: Tablet core: microcrystalline cellulose, calcium hydrogen phosphate dihydrate, croscarmellose sodium, hydroxy propyl cellulose, magnesium stearate. Tablet coating: hypromellose (E464), lactose monohydrate, triacetin (E1518), titanium

dioxide (E171), lake indigo carmine (E132). What Aronix looks like and contents of the

Each tablet is a blue coloured, round film-coated tablet debossed with 'SC' on one

side and '50' on other side. Tablets are packed in boxes of 2, 4, or 8

tablets Not all pack sizes may be marketed. Marketing Authorisation Holder and

Manufacturer Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, East Yorkshire,

HU17 OLD, United Kingdom.

This leaflet was last revised in 12/2020