PACKAGE LEAFLET: INFORMATION FOR THE USER

Azulsix 25 mg, kauwtabletten
Azulsix 50 mg, kauwtabletten
Azulsix 100 mg, kauwtabletten
Sildenafil

Read all of 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:
1. What /../ is and what it is used for
2. Before you take /../
3. How to take /../
4. Possible side effects
5. How to store /../
6. Further information

1. WHAT /../ IS AND WHAT IT IS USED FOR

Sildenafil belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. 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. You should not take sildenafil if you do not have erectile dysfunction. You should not take sildenafil if you are a woman.

/../ is a treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

2. BEFORE YOU TAKE /../

Do not take /../
- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite (“poppers”), as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of /../.
- If you have a severe heart or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.
- If you have certain rare inherited eye diseases (such as *retinitis pigmentosa*).

- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Take special care with /../
- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you have a deformity of your penis or Peyronie's Disease.
- If you have problems with your heart. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking /../ and contact your doctor immediately.

You should not use /../ with any other oral or local treatments for erectile dysfunction.

Special considerations for children and adolescents
/../ should not be given to individuals under the age of 18.

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.

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

/../ chewable tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell any health care professional treating your condition that you have taken /../ and when you did. Do not take /../ with other medicines unless your doctor tells you that you can.

You should not take /../ if you are taking medicines called nitrates, as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take /../ if you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a potentially dangerous decrease in your blood pressure.

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 /../.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement 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 /../ with alpha-blockers. This is most likely to occur within 4 hours after taking /../. 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 /../. Your doctor may start you on a lower dose (25 mg) of /../.

Tell your doctor or pharmacist if you are taking medicines containing sacubitril/valsartan, used to treat heart failure.

Taking /../ with food and drink
/../ can be taken with or without food. However, you may find that /../ takes longer to start working if you take it with a heavy meal.

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking /../.

Pregnancy and breast-feeding
/../ is not indicated for use by women.

Driving and using machines
/../ can cause dizziness and can affect vision. You should be aware of how you react to /../ before you drive or use machinery.

Important information about some of the ingredients of /../
/../ chewable tablets contain aspartame, a source of phenylalanine. If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism) you should take this into account.

/../ chewable tablets contain lactose. . If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE /../
Always take /../ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose is 50 mg.

You should not take /../ more than once a day.

You should take /../ about one hour before you plan to have sex. The tablet should be chewed whole and then swallowed.

If you have the impression that the effect of /../ is too strong or too weak, talk to your doctor or pharmacist.

/../ will only help you to get an erection if you are sexually stimulated. The amount of time /../ takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that /../ takes longer to work if you take it with a heavy meal.

If /../ does not help you to get an erection, or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

If you take more /../ than you should
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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, /../ can cause side effects although not everybody gets them. The side effects reported in association with the use of /../ are usually mild to moderate and of a short duration.

If you have chest pains during or after intercourse:
- Get in a semi-sitting position and try to relax.
- Do not use nitrates to treat your chest pain.
- Contact your doctor immediately.

All medicines including /../ can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking /../: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking /../. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

If you experience a sudden decrease or loss of vision, stop taking /../ and contact your doctor immediately.

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

Common (may affect up to 1 in 10 people): Facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision) stuffy nose and dizziness

Uncommon (may affect up to 1 in100 people): Vomiting, skin rash, bleeding at the back of the eye, eye irritation, bloodshot eyes /red eyes, eye pain, double vision, abnormal sensation in the eye, irregular or rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, chest pain and feeling tired

Rare (may affect up to 1 in 1,000 people): High blood pressure, low blood pressure, fainting, stroke, nosebleed and sudden decrease or loss of hearing

Additional side effects reported from post-marketing experience include: pounding heartbeat, chest pain, sudden death, heart attack or temporary decreased blood flow to parts of the brain. Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to /../. Cases of convulsions or seizures and serious skin reactions characterised by rash, blisters, peeling skin and pain which require immediate medical attention have also been reported.

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 /../
Keep out of the reach and sight of children.

Do not use your medicine after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions; store in the original packaging to protect from light.

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
What /../ contains
x The active substance is sildenafil 25 mg, 50 mg or 100 mg.
The other ingredients are: polacrilin potassium, silica colloidal anhydrous, lactose monohydrate, povidone K-30, aspartame (E951), croscarmellose sodium, peppermint flavour, ~~and~~ magnesium stearate, potassium hydroxide (for pH adjustment) or hydrochloric acid (for pH adjustment).

What /../ looks like and contents of the pack
25 mg: White, triangular, biconvex, embossed with "25" on one side.
50 mg: White, triangular, biconvex, embossed with "50" on one side.
100 mg: White, triangular, biconvex, embossed with "100" on one side

Blisters in packages of:

NL/H/2244/001/DC: 2, 4, 8 and 12 chewable tablets
NL/H/2244/002/DC: 1, 2, 4, 8, 12 chewable tablets
NL/H/2244/003/DC: 2, 4, 8 and 12 chewable tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Farmalider, S.A
C/Aragoneses,15 28108
Madrid
Spanje

Manufacturer:
Genepharm S.A., 18km Marathon Avenue, 15351 Pallini, Greece

In het register ingeschreven onder:
Azulsix 25 mg, kauwtabletten RVG 109181

Azulsix 50 mg, kauwtabletten RVG 109182
Azulsix 100 mg, kauwtabletten RVG 109183

This medicinal product is authorised in the Member States of the EEA under the following names:
Azulsix 25/50/100mg (Netherlands, Spain)

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2022