

Udenafil (100mg, 200mg)

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What Zydena® is used for

Zydena® is used for treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for sexual performance. In order for Udenafil to be effective, sexual stimulation is required.

How Zydena® works

Zydena®, an oral therapy for the treatment of erectile dysfunction, is a selective inhibitor of cyclic guanosine monophosphate(cGMP)-specific phosphodiesterase type 5 (PDE5) of the corpus cavernosum, which induce potent penile erection.

Before you use Zydena®

- When you must not use it

- 1) Patients with a known hypersensitivity to any component of the tablet.
- 2) Patients who receive regular or intermittent nitrate/nitrate/oxide (NO) donor drugs.
- 3) Patients for whom sexual activity is not recommended due to underlying cardiovascular diseases (e.g unstable angina or severe heart failure)
- 4) Patients with stroke, myocardial infarction(MI) or a history of coronary artery bypass surgery within the last 6 months.
- 5) Patients with hypotension(<90/50mmHg); uncontrolled hypertension(>170/100mmHg) or uncontrolled arrhythmias
- 6) Patients with known hereditary degenerative retinal disorders, including retinitis pigmentosa.
- 7) Patients with severe liver failure or renal failure.
- 8) Patients administering potent

- cytochrome P450 3A4 inhibitors (HIV protease inhibitor indinavir or ritonavir).
- 9) Patients using other treatments for erectile dysfunction. The safety and efficacy of concomitant use with other treatments for erectile dysfunction have not been established; use is not recommended.
 - 10) Patients with congenital QT prolongation syndrome, or who are on drugs that increase the QT interval.
 - 11) Patients under 18 years of age.
 - 12) Because this medicine contains lactose, patients with genetic problems such as galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not administer Zydena®.
 - 13) Concomitant use of Zydena® and a Guanylate Cyclase (GC) stimulator (e.g. riociguat) is contraindicated, as PDE5 inhibitors, including Zydena®, may potentiate the hypotensive effects of GC stimulators.

- Before you start to use it

Pregnancy, Lactation and Pediatrics
Zydena® is contraindicated in neonates, pediatrics or women.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Zydena®

- How much to use

- 1) For adult males: Take 100mg orally once a day, approximately 30 minutes to 12 hours prior to sexual activity. Maximum recommended dosing frequency is once daily. Dosage may be increased to 200 mg with caution after adverse reactions are closely examined at 100 mg. Zydena® may be taken with or without food.
- 2) For the Elderly (Over 65 years): Dose adjustment not necessary.
- 3) For patients with renal impairment: Dose adjustment not necessary in

- male patients with mild renal impairment.
- 4) For patients with hepatic impairment: Dose adjustment not necessary for patients with mild hepatic impairment (Child-Pugh Class A).

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Zydena® for the duration that the doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause headache, facial flushing, etc. In case of an overdose, symptomatic therapy should be initiated in general.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Zydena®

Take Zydena® only with a doctor's prescription.

- Things you must not do

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Zydena® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Patients who experience erection lasting longer than 4 hours should be instructed to seek immediate medical attention. If not treated, tissue damage and permanent loss of erection may occur.

Side effects

Like all medicines, Zydena® can cause side effects, although not everybody gets them.

The most common side effects are headache and facial flushing

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of Zydena®**- Storage**

Keep out of the reach and sight of children.

Store in tight containers, below 30°C

Keep the drug in the original package as transferring the drug into other containers may cause accidents and is not desirable in terms of maintaining the quality of the drug

- 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**

Pale-orange, oval, film-coated tablet

- Ingredients

Zydena® 100mg tablets: One tablet(258mg) contains

- Active ingredient: Udenafil---100mg
- Inactive ingredients
 - Additive (tar color): Sunset Yellow FCF Aluminum Lake
 - Other additives: Light anhydrous silicic acid, Titanium oxide, Magnesium stearate, Corn starch, Lactose hydrate, Low substituted hydroxypropylcellulose, Talc, Hydroxypropylcellulose, Hypromellose 2910

Zydena® 200mg tablet: One tablet(516mg) contains

- Active ingredient: Udenafil---200mg
- Inactive ingredients
 - Additive (tar color): Sunset Yellow FCF Aluminum Lake
 - Other additives: Light anhydrous silicic acid, Titanium oxide, Magnesium stearate, Corn starch, Lactose hydrate, Low substituted hydroxypropylcellulose, Talc, Hydroxypropylcellulose, Hypromellose 2910

- MAL number(s):

100mg: MAL20091986AZ

200mg: MAL20091987AZ

Manufacturer

Dong-A ST Co., Ltd.
200-23, Baekseokgongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do (2F Section B, 3F, 4F Section B), Korea

Product Registration Holder

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41050 Klang, Selangor, Malaysia

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