Approved Patient Information Leaflet

Note: The under-mentioned information is consistent with the information in the Proposed Package Insert for **ZELDINA 25, 50 & 100 mg**.

SCHEDULING STATUS: **S4**

PROPRIETARY NAMES (AND DOSAGE FORMS)

ZELDINA 25 mg (chewable tablets)

ZELDINA 50 mg (chewable tablets)

ZELDINA 100 mg (chewable tablets)

Read this leaflet carefully before ZELDINA is used.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you or you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ZELDINA CONTAINS

ZELDINA 25 mg: Each chewable tablet contains sildenafil citrate equivalent to 25 mg.

ZELDINA 50 mg: Each chewable tablet contains sildenafil citrate equivalent to 50 mg.

ZELDINA 100 mg: Each chewable tablet contains sildenafil citrate equivalent to 100 mg.

ZELDINA chewable tablets also contain the following inactive ingredients: polacrilin potassium, silica colloidal anhydrous, lactose monohydrate, povidone K-30, aspartame (E951), croscarmellose sodium, peppermint flavor and magnesium stearate.

Contains sugar (lactose monohydrate)

Contains sweetener (aspartame)

2. WHAT ZELDINA IS USED FOR

ZELDINA 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 the blood to flow into your penis when you get sexually excited. **ZELDINA** will only help you get an erection if you are sexually stimulated.

ZELDINA is used for the treatment of erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. You should not take **ZELDINA** if you do not have erectile dysfunction.

3. BEFORE USING ZELDINA

Do not take ZELDINA if you

- are hypersensitive (allergic) to sildenafil or any of the ingredients of **ZELDINA**
- have a severe heart or liver problem
- have recently had a stroke or a heart attack, or if you have low blood pressure
- are under the age of 18 years
- are a woman
- are taking any of the medicines known as nitric oxide donors (such as amyl nitrite) or nitrates, as the combination may lead to a potentially dangerous decrease in your blood pressure
- have loss of vision in one eye or have certain rare inherited eye diseases such as retinitis pigmentosa (eye disease with damage to the retina)
- you are using medication such as erythromycin (an antibiotic), ritonavir or saquinavir (medicines used to treat HIV), ketoconazole or itraconazole (anti-fungal medicines).

Take special care with ZELDINA

The presence of other medical problems may affect the use of **ZELDINA**.

Talk to your doctor, pharmacist or healthcare professional before taking **ZELDINA** if you:

- have pre-existing cardiovascular disease (especially if you have problems with your heart or the valves of your heart- conditions such as aortic stenosis or hypertrophic obstructive cardiomyopathy)
- are taking any blood pressure medication
- are having bleeding disorders or peptic ulcers
- are experiencing prolonged and painful erections of the penis
- have a deformity of your penis or Peyronie's Disease
- have problems with your heart. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex
- currently have a stomach ulcer, or bleeding problems (such as haemophilia)
- experience sudden decrease or loss of vision, stop taking **ZELDINA** and contact your doctor immediately
- have kidney or liver problems. Your doctor may decide on a lower dose for you
- if you suffer from a nervous system (neurological) disorder called multiple system atrophy which has impaired your body's ability to regulate your blood pressure, inform your doctor as ZELDINA may cause a dangerous drop in your blood pressure
- if you are taking a medication called an alpha-blocker (usually used in the treatment of high blood pressure or prostate enlargement) your doctor will do tests before deciding whether you can take ZELDINA or may prescribe a lower dose for you.

Taking ZELDINA with food and drink

ZELDINA can be taken with or without food. However, you may find that **ZELDINA** 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 **ZELDINA**.

Pregnancy and Breast-feeding

ZELDINA is not indicated for use by women.

Effects on ability to drive and use machinery

You are advised not to drive a car or operate machinery until you know how **ZELDINA** affects you as it may cause drowsiness.

Important information about some of the ingredients of ZELDINA

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

Using other medicines with ZELDINA

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

ZELDINA 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 **ZELDINA** and when you did. Do not take **ZELDINA** with other medicines unless your doctor tells you that you can.

You should not take **ZELDINA** 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 **ZELDINA** if you are using any of the medicines known as nitric oxide donors such as amyl nitrite 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 (ritonavir and saquinavir which are used for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of **ZELDINA.**

If you are taking erythromycin (an antibiotic) or ketoconazole or itraconazole (anti-fungal medicines.

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 **ZELDINA** with alpha-blockers. This is most likely to occur within 4 hours after taking **ZELDINA**. 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 **ZELDINA**. Your doctor may start you on a lower dose (25 mg) of **ZELDINA**.

4. HOW TO USE ZELDINA

Do not share medicines prescribed for you with any other person.

Always take **ZELDINA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that **ZELDINA** is too strong or too weak, you should talk to your doctor or pharmacist.

Take **ZELDINA** once daily. The recommended dose is 50 mg, taken approximately one hour before sexual activity. The dose may be increased to 100 mg or decreased to 25 mg. The maximum recommended daily dose is 100 mg.

ZELDINA is not recommended for use in children and individuals below 18 years of age.

You should not take ZELDINA more than once a day.

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

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

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

If **ZELDINA** 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 ZELDINA 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.

5. POSSIBLE SIDE-EFFECTS

ZELDINA may cause side effects. Check with your doctor, pharmacist or healthcare professional if any of these side effects persist or become bothersome.

If any of the following happens, stop taking ZELDINA and contact your doctor immediately or go to the nearest hospital, as you may need urgent medical attention:

- Wheezing and having difficulty breathing, swelling of your eyelids, throat, lips and face, severe itching of your skin (these may be signs of an allergic reaction to **ZELDINA**)
- Chest pains
- Sudden decrease or loss of vision

If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

If any of the following continue to become bothersome, you may need medical attention:

The following side effects occur frequently: flu syndrome, headache, dizziness, visual colour distortion such as blurred vision or seeing things “too brightly”, flushing (increased blood flow), nasal congestion (runny nose), dyspepsia (upset stomach or indigestion).

The following side effects occur less frequently: respiratory tract infections and urinary tract infections, anaemia (a decrease in your red blood cells- you may feel tired and look pale), leucopenia (a decrease in your white blood cells- you may notice that you get sick or flu-ish more often), gout, somnolence (sleepiness) or insomnia (being unable to sleep), eye disorders (pain in the eye, being sensitive to light or dry eyes), anorgasmia (being unable to reach orgasm), hypoaesthesia (decreased sensitivity to touch), vertigo (dizziness), tinnitus (abnormal noise in the ear), vomiting and nausea, dry mouth, myalgia (muscle pain), arthralgia (pain in the joints), chest pain, fatigue (unusual tiredness), and increased heart rate, feeling dizzy when standing up after you have been sitting or lying down (postural hypotension), skin rash and itchy skin, abnormal ejaculation, breast enlargement and genital oedema (swelling of the genitals)

Other possible side-effects include:

Cerebro-vascular accident (stroke), deafness, hypertension (high blood pressure), hypotension (dizziness, light-headedness, or fainting), epistaxis (bleeding of the nose), sudden cardiac death, myocardial infarction (heart attack).

Not all side-effects reported for **ZELDINA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ZELDINA**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORAGE AND DISPOSING OF ZELDINA

Store at or below 25 °C. Store in the original packaging (keep blisters in the carton until required for use, in order to protect them from light).

Do not store your medicine in the bathroom.

Do not use **ZELDINA** after the expiry date printed on the label, container or blister.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ZELDINA OUT OF REACH OF CHILDREN.

7. PRESENTATION OF ZELDINA

ZELDINA chewable tablets are packed in transparent PVC/PCTFE aluminium foil blisters containing 1, 2, 4, 8 or 12 chewable tablets, packed in a cardboard carton. Not all pack sizes may be marketed at any one time.

8. IDENTIFICATION OF ZELDINA

ZELDINA 25 mg:

White, triangular, biconvex tablet, embossed with “25” on one side**.**

ZELDINA 50 mg:

White, triangular, biconvex tablet, embossed with “50” on one side

ZELDINA 100 mg:

White, triangular, biconvex tablet, embossed with “100” on one side.

9. REGISTRATION NUMBER

ZELDINA 25 mg: 46/7.1.5/0801

ZELDINA 50 mg: 46/7.1.5/0802

ZELDINA 100 mg: 46/7.1.5/0803

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals Pty (Ltd)

1 Sherborne Road

Parktown

Johannesburg, 2193

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11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date on the registration certificate of the medicine: 20 April 2017

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