

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

Sildenafil Zentiva 25 mg film-coated tablets  
Sildenafil Zentiva 50 mg film-coated tablets  
Sildenafil Zentiva 100 mg film-coated tablets

Sildenafil

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Sildenafil Zentiva is and what it is used for
2. What you need to know before you take Sildenafil Zentiva
3. How to take Sildenafil Zentiva
4. Possible side effects
5. How to store Sildenafil Zentiva
6. Contents of the pack and other information

### **1. What Sildenafil Zentiva is and what it is used for**

Sildenafil Zentiva contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) 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 Zentiva will only help you to get an erection if you are sexually stimulated.

Sildenafil Zentiva is a treatment for adult 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. What you need to know before you take Sildenafil Zentiva**

#### **Do not take Sildenafil Zentiva**

- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall 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 medicines known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a dangerous fall in your blood pressure.
- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- 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)

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Sildenafil Zentiva

- 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 carefully check whether your heart can take the additional strain of having sex.
- 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 Sildenafil Zentiva and contact your doctor immediately.

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

You should not take Sildenafil Zentiva if you do not have erectile dysfunction.

You should not take Sildenafil Zentiva 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**

Sildenafil Zentiva should not be given to individuals under the age of 18.

### **Other medicines and Sildenafil Zentiva**

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

Sildenafil Zentiva film-coated 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 or pharmacist that you have taken Sildenafil Zentiva and when you did. Do not take Sildenafil Zentiva with other medicines unless your doctor tells you that you can.

You should not take Sildenafil Zentiva if you are taking medicines called nitrates as the combination of these medicines may lead to a dangerous fall 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 Sildenafil Zentiva if you are using any of the medicines known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a dangerous fall 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 Sildenafil Zentiva.

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 sildenafil with alpha-blockers. This is most likely to happen within 4 hours after taking sildenafil. In order to reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil Zentiva. Your doctor may start you on a lower dose (25 mg) of Sildenafil Zentiva.

#### **Sildenafil Zentiva with food, drink and alcohol**

Sildenafil Zentiva can be taken with or without food. However, you may find that Sildenafil Zentiva 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 Sildenafil Zentiva.

#### **Pregnancy, breast feeding and fertility**

Sildenafil Zentiva is not indicated for use by women.

#### **Driving and using machines**

Sildenafil Zentiva can cause dizziness and can affect vision. You should be aware of how you react to Sildenafil Zentiva before you drive or use machinery.

#### **Sildenafil Zentiva contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking Sildenafil Zentiva.

### **3. How to take Sildenafil Zentiva**

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

*You should not take Sildenafil Zentiva more than once a day.*

Do not take Sildenafil Zentiva film-coated tablets in combination with sildenafil containing orodispersible tablets.

You should take Sildenafil Zentiva about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

If you feel that the effect of Sildenafil Zentiva is too strong or too weak, talk to your doctor or pharmacist.

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

If Sildenafil Zentiva 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.

The tablet can be divided into equal halves.

**If you take more Sildenafil Zentiva 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, this medicine can cause side effects although not everybody gets them. The side effects reported in association with the use of Sildenafil Zentiva are usually mild to moderate and of a short duration.

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

- An allergic reaction (this occurs rarely)  
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pains (this occurs uncommonly): If this occurs during or after intercourse
  - Get in a semi-sitting position and try to relax.
  - **Do not use nitrates** to treat your chest pain.

- Prolonged and sometimes painful erections (frequency unknown). If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.
- A sudden decrease or loss of vision (**frequency unknown**).
- Serious skin reactions (**frequency unknown**).  
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits (**frequency unknown**)

**Other side effects:**

**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, dizziness.

**Uncommon** (may affect up to 1 in 100 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, watery eyes, pounding heartbeat, rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, penile bleeding, presence of blood in semen and/or urine, chest pain and feeling tired.

**Rare** (may affect up to 1 in 1,000 people): high blood pressure, low blood pressure, fainting, stroke, heart attack, irregular heartbeat, nosebleed and sudden decrease or loss of hearing.

**Not known** (frequency cannot be estimated from the available data):

Additional side effects reported from post-marketing experience:

Unstable angina (a heart condition) sudden death, temporary decreased blood flow to parts of the brain. 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 sildenafil.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Sildenafil Zentiva**

Keep this medicine 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 label 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 information**

### **What Sildenafil Zentiva contains**

The active substance is sildenafil.

Each film-coated tablet contains 25 mg of sildenafil (as 35,12 mg sildenafil citrate ).

Each film-coated tablet contains 50 mg of sildenafil (as 70,24 mg sildenafil citrate).

Each film-coated tablet contains 100 mg of sildenafil (as 140,48 mg sildenafil citrate).

The other ingredients are:

- Tablet core : microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate
- Tablet coating: lactose monohydrate, hypromellose, titanium dioxide (E171), triacetin, indigo carmine aluminium lake (E132)

### **What Sildenafil Zentiva looks like and contents of the pack**

Sildenafil Zentiva 25 mg film-coated tablet

Blue coloured round, biconvex, film-coated tablets debossed with 124 on one side and J on the other side.

Sildenafil Zentiva 50 mg film-coated tablet

Blue coloured round, scored biconvex, film-coated tablets debossed with 125 on one side and J on the other side with the score line. The tablet can be divided into equal doses.

Sildenafil Zentiva 100 mg film-coated tablet

Blue coloured round, biconvex, scored film-coated tablets debossed with 126 on one side and J on the other side with the score line. The tablet can be divided into equal doses.

**Sildenafil Zentiva is supplied in the following pack sizes:**

PT/H/0612/001-003 Sildenafil Zentiva 25/50/100 mg film-coated tablet TXT EN type II variation after RUP 09\_2013

**Sildenafil Zentiva 25 mg film-coated tablets**

PVC/Aluminium foil blisters in cartons of 1, 2, 4, 8 or 12 tablets.

**Sildenafil Zentiva 50 mg film-coated tablets**

PVC/Aluminium foil blisters in cartons of 1, 2, 4, 8 or 12 tablets.

**Sildenafil Zentiva 100 mg film-coated tablets**

PVC/Aluminium foil blisters in cartons of 1, 2, 4, 8 or 12 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

Sanofi-Aventis Ireland Limited T/A Sanofi  
Citywest Business Campus  
Dublin 24  
Ireland

Manufacturer

Zentiva RO  
S.C. Zentiva S.A.  
B-dul. Theodor Pallady nr.50, sector 3,  
Bucuresti, cod 032266  
Romania

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Portugal, Italy	SILDENAFIL ZENTIVA
Cyprus, Greece	Sildenafil/Zentiva
Germany, Ireland, United Kingdom, Slovenia	Sildenafil Zentiva 25/50/100 mg
Spain	Sildenafil Zentiva 25/50/100 mg

**This leaflet was last revised in 12/2014.**