

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### SILDENA

25mg film-coated tablets

#### SILDENAFIL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 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 or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What SILDENAFIL is and what it is used for
2. Before you take SILDENAFIL
3. How to take SILDENAFIL
4. Possible side effects
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#### 1. WHAT SILDENAFIL IS AND WHAT IS IT USED FOR

The name of your medicine is SILDENA 25mg film-coated tablets (referred to as SILDENAFIL throughout this leaflet).

SILDENA 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 will only help you to get an erection if you are sexually stimulated.

SILDENAFIL 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. BEFORE YOU TAKE SILDENAFIL

##### **Do not take SILDENAFIL**

- 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.
- 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***

- 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 and contact your doctor immediately.

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

You should not take SILDENAFIL if you do not have erectile dysfunction.

You should not take SILDENAFIL 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 should not be given to individuals under the age of 18.

### ***Other medicines and SILDENAFIL***

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

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

You should not take SILDENAFIL 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 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 (25mg) of SILDENAFIL.

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. Your doctor may start you on a lower dose (25mg) of SILDENAFIL.

### ***SILDENAFIL with food, drink and alcohol***

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

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

SILDENAFIL is not indicated for use by women.

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

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

### ***SILDENAFIL 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.

## **3. HOW TO TAKE SILDENAFIL**

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 50mg.

*You should not take SILDENAFIL more than once a day.*

Do not take SILDENAFIL film-coated tablets in combination with SILDENAFIL containing orodispersible tablets. You should take SILDENAFIL 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 is too strong or too weak, talk to your doctor or pharmacist.

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

If SILDENAFIL 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 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 are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking SILDENAFIL 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.

By reporting side effects you can help provide more information on the safety of this medicine.

***5. HOW TO STORE SILDENAFIL***

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.