

## Package leaflet: Information for the patient

/.../ 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, 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. See section 4.

### What is in this leaflet:

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

### 1. What /.../ is and what it is used for

/.../ contains the active substance sildenafil which 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. /.../ will only help you to get an erection if you are sexually stimulated.

/.../ 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 /.../

#### Do not take /.../

- if you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- 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 taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as /.../ have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- 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).

### **Warning and precautions**

Talk to your doctor or pharmacist before taking /.../

- 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 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.

You should not use /.../ with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

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

You should not take /.../ 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**

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

### **Other medicines and /.../**

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

/.../ 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, pharmacist 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 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 /.../ 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.

Tell your doctor or pharmacist if you are already taking riociguat.

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).

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 happen within 4 hours after taking /.../. To reduce the chance that these symptoms might happen, 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).

**/.../ with food, drink and alcohol**

/.../ 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, breast feeding and fertility**

/.../ 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.

**/.../ contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

**3. How to take /.../**

Always take this medicine exactly as your doctor or pharmacist 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 /.../ more than once a day.*

Do not take /.../ film-coated tablets in combination with other sildenafil orodispersible tablets.

You should take /.../ 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 /.../ 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.

The tablet can be divided into equal halves to obtain the 50 mg dose. For administration of 25 mg dose you should use different medicine.

**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, this medicine 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 experience any of the following serious side effects stop taking /.../ and seek medical help immediately:**

- An allergic reaction - this occurs **uncommonly** (may affect up to 1 in 100 people)  
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 - this occurs **rarely** (may affect up to 1 in 1,000 people)  
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 - this occurs **rarely**
- Serious skin reactions - this occurs **rarely**  
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits -this occurs **rarely**

#### **Other side effects:**

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

- headache.

**Common** (may affect up to 1 in 10 people)

- nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual disturbance, stuffy nose and dizziness.

**Uncommon** (may affect up to 1 in 100 people)

- vomiting, skin rash, eye irritation, bloodshot eyes /red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms

include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

**Rare** (may affect up to 1 in 1,000 people)

- fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, 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 /.../.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V\*. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store /.../**

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. The expiry date refers to the last day of the 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 /.../ contains**

The active substance is sildenafil. Each film-coated tablet contains 100 mg of sildenafil (as citrate salt).

The other ingredients are:

- Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate
- Tablet coating: Opadry II blue 85F505164 (polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, indigo carmine aluminium lake (E132)) and Opadry clear 02K19253 (hypromellose, triacetin)

### **What /.../ looks like and contents of the pack**

Blue coloured round, biconvex, film coated tablets debossed with 126 on one side and J on the other side with the score line.

Pack size: 1, 2, 4, 8, 10, 12, 20, 24, 28 or 90 film-coated tablets in PVC/Aluminium or PVC/PVDC/Aluminium blisters.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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

<To be completed nationally>

**This leaflet was last revised in** <To be completed nationally>.