

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Sildenafil Medical Valley 20 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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

#### **1. What [Invented name] is and what it is used for**

[Invented name] contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

[Invented name] brings down blood pressure in the lungs by widening the blood vessels in the lungs.

[Invented name] is used to treat adults and children and adolescents from 1 to 17 years old with high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension).

#### **2. What you need to know before you take [Invented name]**

##### **Do not take [Invented name]:**

- if you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- if you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of chest pain (or “angina pectoris”). [Invented name] can cause a serious increase in the effects of these medicines. Tell your doctor if you are taking any of these medicines. If you are not certain, ask your doctor or pharmacist.
- 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

[Invented name] 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 recently had a stroke, a heart attack or if you have severe liver disease or very low blood pressure (<90/50 mmHg).
- if you are taking a medicine to treat fungal infections such as ketoconazole or itraconazole or medicines containing ritonavir (for HIV).
- if you have ever had loss of vision because of a problem with blood flow to the nerve in the eye called non-arteritic anterior ischaemic optic neuropathy (NAION).

### **Warnings and precautions**

Talk to your doctor before taking [Invented name] if you:

- have a disease due to a blocked or narrow vein in the lungs rather than a blocked or narrow artery.
- have a severe heart problem.
- have a problem with the pumping chambers of your heart
- have high blood pressure in the blood vessels in the lungs.
- have low blood pressure at rest.
- lose a large amount of body fluids (dehydration) which can occur when you sweat a lot or do not drink enough liquids. This can happen if you are sick with a fever, vomiting, or diarrhoea.
- have a rare inherited eye disease (*retinitis pigmentosa*).
- have an abnormality of red blood cells (sickle cell anaemia), cancer of blood cells (leukaemia), cancer of bone marrow (multiple myeloma), or any disease or deformity of the penis.
- currently have a stomach ulcer, a bleeding disorder (such as haemophilia) or problems with nose bleeds.
- take medicines for erectile dysfunction.

When used to treat male erectile dysfunction (ED), the following visual side effects have been reported with PDE5 inhibitors, including sildenafil at an unknown frequency; partial, sudden, temporary, or permanent decrease or loss of vision in one or both eyes.

If you experience sudden decrease or loss of vision, **stop taking [Invented name] and contact your doctor immediately** (see also section 4).

Prolonged and sometimes painful erections have been reported in men after taking sildenafil. If you have an erection, which lasts continuously for more than 4 hours, **stop taking [Invented name] and contact your doctor immediately** (see also section 4).

#### *Special considerations for patients with kidney or liver problems*

You should tell your doctor if you have kidney or liver problems, as your dose may need to be adjusted.

### **Children**

[Invented name] should not be given to children below 1 year of age.

**Other medicines and [Invented name]**

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

- Medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of angina pectoris or “chest pain” (see section 2. Before you take [Invented name])
- Tell your doctor or pharmacist if you are already taking riociguat
- Therapies for pulmonary hypertension (e.g. bosentan, iloprost)
- Medicines containing St. John’s Wort (herbal medicinal product), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin and phenobarbital (used, among others, to treat epilepsy)
- Blood thinning medicines (for example warfarin) although these did not result in any side effect.
- Medicines containing erythromycin, clarithromycin, telithromycin (these are antibiotics used to treat certain bacterial infections), saquinavir (for HIV) or nefazodone (for mental depression), as your dose may need to be adjusted.
- Alpha-blocker therapy (e.g. doxazosin) for the treatment of high blood pressure or prostate problems, as the combination of the two medicines may cause symptoms resulting in the lowering of your blood pressure (e.g. dizziness, light headedness).
- Medicines containing sacubitril/valsartan, used to treat heart failure

**[Invented name] with food and drink**

You should not drink grapefruit juice while you are being treated with [Invented name].

**Pregnancy and breast-feeding**

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. [Invented name] should not be used during pregnancy unless strictly necessary.

[Invented name] should not be given to women of child bearing potential unless using appropriate contraceptive methods.

[Invented name] passes into your breast milk at a very low levels and would not be expected to harm your baby.

**Driving and using machines**

[Invented name] can cause dizziness and can affect vision. You should be aware of how you react to the medicine before you drive or use machines.

**[Invented name] contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’

### **3. How to take [Invented name]**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For adults, the recommended dose is 20 mg three times a day (taken 6 to 8 hours apart) taken with or without food.

#### **Use in children and adolescents**

For children and adolescents aged 1 year to 17 years old, the recommended dose is either 10mg three times a day for children and adolescents  $\leq 20$  kg or 20 mg three times a day for children and adolescents  $> 20$  kg, taken with or without food. Higher doses should not be used in children. This medicine should be used only in case of administration of 20 mg three times a day. Other pharmaceutical forms may be more appropriate for administration to patients  $\leq 20$  kg and other younger patients who are not able to swallow tablets.

#### **If you take more [Invented name] than you should**

You should not take more medicine than your doctor tells you to.

If you take more medicine than you have been told to take contact your doctor immediately. Taking more [Invented name] than you should may increase the risk of known side effects.

#### **If you forget to take [Invented name]**

If you forget to take [Invented name], take a dose as soon as you remember, then continue to take your medicine at the usual times. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking [Invented name]**

Suddenly stopping your treatment with [Invented name] may lead to your symptoms getting worse. Do not stop taking [Invented name] unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, [Invented name] can cause side effects, although not everybody gets them.

**If you experience any of the following side effects you should stop taking [Invented name] and contact a doctor immediately** (see also section 2):

- if you experience sudden decrease or loss of vision (frequency not known)
- if you have an erection, which lasts continuously for more than 4 hours. Prolonged and sometimes painful erections have been reported in men after taking sildenafil (frequency not known).

#### **Adults**

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

- headache, facial flushing

- indigestion, diarrhoea
- pain in the arms or legs.

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

- infection under the skin, hair loss, redness of the skin, night sweats
  - flu-like symptoms, bronchitis, inflammation of the sinuses, runny nose, nosebleed, cough, stuffy nose
  - dry mouth
  - reduced number of red blood cells (anaemia)
  - fluid retention
  - difficulty sleeping, anxiety, migraine, shaking, “pins and needles”-like sensation, burning sensation, reduced sense of touch
  - bleeding at the back of the eye, effects on vision, blurred vision and light sensitivity, effects on colour vision, eye irritation, bloodshot eyes /red eyes
  - vertigo
  - gastroenteritis, stomach inflammation, heartburn, piles, abdominal distension
  - muscle aches, back pain
- increased body temperature.

**Uncommon** (may affect 1 in 100 people):

- reduced sharpness of vision, double vision, abnormal sensation in the eye
- penile bleeding, presence of blood in semen and/or urine
- breast enlargement in men.

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

- skin rash
- sudden decrease or loss of hearing
- decreased blood pressure.

### **Children and adolescents**

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

- pneumonia
- heart failure, right heart failure, heart related shock
- high blood pressure in the lungs, chest pain, fainting, respiratory infection, bronchitis
- viral infection in the stomach and intestines
- urinary tract infections
- tooth cavities.

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

- allergic reaction (such as skin rash, swelling of the face, lips and tongue, wheezing, difficulty breathing or swallowing)
- convulsion
- irregular heart-beat
- hearing impairment
- shortness of breath
- inflammation of the digestive tract

- wheezing due to disrupted airflow.

Other side effects:

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

- infection of the throat, headache
- vomiting
- fever
- diarrhoea
- flu
- nosebleed

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

- increased erections
- nausea
- pneumonia and runny nose.

### **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 [Invented name]**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What [Invented name] contains**

- The active substance is sildenafil. Each tablet contains 20 mg of sildenafil (as the citrate).
- The other ingredients are:
  - Tablet core: microcrystalline cellulose (E460), calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate (E572).
  - Film coat: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, triacetin

**What [Invented name] looks like and contents of the pack**

White to off white colored, round shaped, biconvex, film coated tablets debossed with 'J' on one side '95' and on the other side.

[Invented name] 20 mg film-coated tablets are supplied in PVC/Aluminium and PVC/PVdC/Aluminium blister packs containing 30, 90, 100, and 300 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

<To be completed nationally>

Manufacturer  
Pharmadox Healthcare Limited  
KW20A Kordin Industrial Park, Paola  
PLA 3000  
Malta

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

SE	Sildenafil Medical Valley 20 mg filmdragerade tablett
NO	Sildenafil Medical Valley 20 mg filmdrasjerte tablett
IS	Sildenafil Medical Valley 20 mg filmhúðuð tafla

**This leaflet was last revised in MM/YYYY.**

2022-10-20