

PATIENT INFORMATION LEAFLET  
SILDENAFIL 10MG/ML ORAL SUSPENSION

{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, 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 Oral suspension is and what it is used for
2. What you need to know before you take Sildenafil Oral suspension
3. How to take Sildenafil Oral suspension
4. Possible side effects
5. How to store Sildenafil Oral suspension

**1. What Sildenafil Oral suspension is and what it is used for**

Sildenafil Oral suspension contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. Sildenafil Oral suspension brings down blood pressure in the lungs by widening the blood vessels in the lungs. Sildenafil Oral suspension 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 Sildenafil Oral suspension**

**Do not take Sildenafil Oral suspension:**

- 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”). Sildenafil Oral suspension 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 Sildenafil Oral suspension 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 Sildenafil Oral suspension 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 Sildenafil Oral suspension 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 Sildenafil Oral suspension 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

Sildenafil Oral suspension should not be given to children below 1 year of age.

## Other medicines and Sildenafil Oral suspension

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 Sildenafil Oral suspension).
- 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 of low blood pressure (e.g. dizziness, light headedness).

## Sildenafil Oral suspension with food and drink

You should not drink grapefruit juice while you are being treated with Sildenafil Oral suspension.

## 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. Sildenafil Oral suspension should not be used during pregnancy unless strictly necessary. Sildenafil Oral suspension should not be given to women of child bearing potential unless using appropriate contraceptive methods. Sildenafil Oral suspension passes into your breast milk at very low levels and would not be expected to harm your baby.

## Driving and using machines

Sildenafil Oral suspension can cause dizziness and can affect vision. You should be aware of how you react to the medicine before you drive or use machines.

## Sildenafil Oral suspension contains sodium benzoate:

- Sodium benzoate (E211). This medicine contains 2.0 mg sodium benzoate in each ml.
- This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

## 3. How to take Sildenafil Oral suspension

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 (2 ml of Oral suspension) 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 10 mg (1 ml of Oral suspension) three times a day for children and adolescents weighing 20 kg or under, or 20 mg (2 ml of Oral suspension) three times a day for children and adolescents weighing over 20 kg, taken with or without food.

Higher doses should not be used in children.

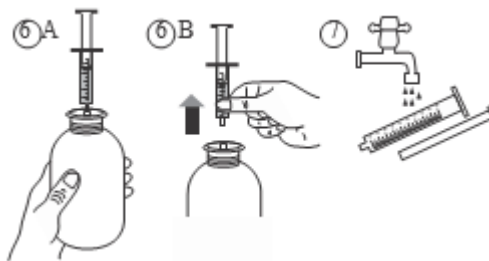
## Instructions for use

The oral suspension must be shaken well before use.

- Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.



- c. Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).
- d. Fill the syringe with a small amount of suspension by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).
- e. Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).
- f. Close the bottle with the plastic screw cap.
- g. Empty the contents of the syringe into your mouth.
- h. After dosing, wash the syringe with water only (figure 7).



#### **If you take more Sildenafil Oral suspension 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 Sildenafil Oral suspension than you should may increase the risk of known side effects.

#### **If you forget to take Sildenafil Oral suspension**

If you forget to take Sildenafil Oral suspension, 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 Sildenafil Oral suspension**

Suddenly stopping your treatment with Sildenafil Oral suspension may lead to your symptoms getting worse. Do not stop taking Sildenafil Oral suspension 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, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, you should stop taking Sildenafil Oral suspension 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

Side effects reported very commonly (may affect more than 1 in 10 people) were headache, facial flushing, indigestion, diarrhoea and pain in the arms or legs.

Side effects reported commonly (may affect up to 1 in 10 people) included: infection under the skin, flu-like symptoms, inflammation of the sinuses, 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, bronchitis, nosebleed, runny nose, cough, stuffy nose, stomach inflammation, gastroenteritis, heartburn, piles, abdominal distension, dry mouth, hair loss, redness of the skin, night sweats, muscle aches, back pain and increased body temperature.

Side effects reported uncommonly (may affect up to 1 in 100 people) included: reduced sharpness of vision, double vision, abnormal sensation in the eye, penile bleeding, presence of blood in semen and/or urine, and breast enlargement in men.

Skin rash and sudden decrease or loss of hearing and decreased blood pressure have also been reported at an unknown frequency (frequency cannot be estimated from the available data).

#### Children and adolescents

The following serious adverse events have been reported commonly (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 and tooth cavities.

The following serious adverse events were considered to be treatment related and were reported uncommonly (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.

Side effects reported very commonly (may affect more than 1 in 10 people) were headache, vomiting, infection of the throat, fever, diarrhoea, flu and nosebleed.

Side effects reported commonly (may affect up to 1 in 10 people) were nausea, increased erections, pneumonia and runny nose.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. Please tell your doctor, health care provider or pharmacist.

## **5. How to store Sildenafil Oral suspension**

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

This medicinal product does not require any special storage conditions.

Store in the original package. Do not store above 30°C after first opening of the bottle. Discard after 60 days of first opening.

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

Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

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

### **What Sildenafil Oral suspension contains**

The active ingredient is Sildenafil (as citrate).

Each 1 ml of Sildenafil Oral suspension contains 10 mg of Sildenafil.

The other ingredients are:

Citric Acid Anhydrous Powder, USP

Sodium Citrate Dihydrate Powder, USP

Sodium Benzoate Powder, NF

Sucralose, NF

Xanthan Gum, NF

Colloidal Silicon Dioxide, USP

Art Grape 059145 AP0551

Titanium Dioxide, NF

Sorbitol, USP

### **What Sildenafil Oral suspension looks like and contents of the pack**

Sildenafil Oral suspension is a white to off white suspension.

This medicine is supplied in amber glass bottle with a white child resistant tamper evident closure containing

112 ml of liquid product following the reconstitution .

The package contains a 2 ml oral syringe with a polypropylene body, purple HDPE plunger, graduations printed at 0.5 ml 1.0 ml, 1.5 ml and 2.0 ml together with a low density polyethylene bottle adaptor.

### **The Marketing Authorization Holder and Manufacturer is:**

Novitium Pharma LLC

70 Lake Drive, East Widsor

New Jersey 08520, USA

**This leaflet was revised in:**

**To report any side effect(s):**

- **Saudi Arabia:**

- The National Pharmacovigilance and Drug Safety Center (NPC)
  - Fax: +966 11 205 7662
  - SFDA Call Center: 19999
  - E-mail: npc.drug@sfda.gov.sa
  - Website: www.sfda.gov.sa

- **For other GCC states: please refer to the health authority in your region.**

**This is a medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
  - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
  - The doctor and the pharmacists are experts in medicine, its benefits and risks.
  - Do not by yourself interrupt the period of treatment prescribed for you.
  - Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children

Council of Arab Health Ministers