

**1.3 Product Information**

**1.3.1 SPC, labelling and package leaflet**

**1.3.1.3 Package Leaflet**

## Package leaflet: Information for the patient

### Sildenvia 50 mg film-coated tablets sildenafil

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

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you have taken Sildenvia as directed and were not able to get or keep an erection firm enough for sex.

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

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

#### **1. What Sildenvia is and what it is used for**

##### **What Sildenvia is**

Sildenvia contains the active substance sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by relaxing the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited and causing an erection. Sildenvia will only help you to get an erection if you are sexually excited (stimulated).

##### **What Sildenvia is used for**

Sildenvia is a treatment for men aged 18 years and older with erectile dysfunction.

Erectile dysfunction, also known as impotence, is an inability to achieve or maintain an erection that is firm enough to have sex. Erections depend on many different factors, including proper blood flow to the penis. Reduced blood flow to the penis may cause erectile dysfunction. Erectile dysfunction can affect men differently. Some cannot achieve an erection. Others may achieve an erection, but not firm enough for having sex or they may lose the erection before or during sex.

#### **2. What you need to know before you Sildenvia**

##### **Do not take Sildenvia if you**

- do not have an erection problem
- take any nitrate medicine for chest pain or heart failure (see “Other medicines and Sildenvia”)
- take amyl nitrite, so called “poppers” as recreational drugs
- take riociguat (or other guanylate cyclase stimulators) for high blood pressure in the lungs (see “Other medicines and Sildenvia”)
- take ritonavir for the treatment of HIV (see “Other medicines and Sildenvia”)
- have been advised by your doctor to avoid sexual activity because of a problem with your heart or blood vessels (see “Warnings and precautions”)
- have a severe heart problem such as a recent heart attack or stroke (within the last 6 months), unstable angina (chest pain) or severe cardiac failure (reduced pumping capacity of the heart)
- have a severe liver problem

- have low blood pressure (below 90/50 mmHg) which can cause symptoms such as tiredness, dizziness, light-headedness, feeling sick, clammy skin, depression, loss of consciousness, or blurry vision
- have ever had severe vision loss because of nerve damage in the eyes, such as non-arteritic anterior ischaemic optic neuropathy (NAION); or have a rare inherited eye disease, such as retinitis pigmentosa (see “Warnings and precautions”)
- have a deformed penis
- are a woman
- are under 18 years of age
- are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6)

### Warnings and precautions

You should schedule a health check-up with your doctor as soon as possible within the first 6 months of starting to use Sildenvia to ensure that your erection problems are not caused by any serious health condition.

Erectile dysfunction may be an early sign of:

- cardiovascular disease
- diabetes
- high blood pressure
- high cholesterol

Tell your doctor about your problems if you have not already done so.

#### Cardiovascular risk factors

Sexual activity can put a strain on your heart (see “Do not take Sildenvia if you” above).

Talk to your doctor before taking Sildenvia if you:

- get very breathless or feel any pain in the chest with light or moderate activity (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex.
- have a problem with a valve in your heart (valvular heart disease).
- have a disease in which the heart muscle becomes inflamed and does not work as well as it should (cardiomyopathy).
- have an irregular heart beat (arrhythmia).
- you have had surgery to improve blood flow to your heart, or you have high blood pressure which is now adequately treated.
- have high blood pressure that is not controlled.

#### Other risk factors:

Talk to your doctor before taking Sildenvia if you:

- have ever had an erection that lasted more than 4 hours (priapism).  
Some conditions can increase the probability of having a persistent erection, such as sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow). Use of impotence medicines may increase the risk of priapism. Long lasting erection may cause damage to the tissue in the penis and permanent loss of ability to have an erection.
- have a stomach ulcer or a bleeding disorder (such as haemophilia).
- have previously been diagnosed with mild to moderate liver disease, or severe kidney problems.  
Sildenvia may not be suitable for you, you should consult your doctor before taking Sildenvia.

If you experience any sudden visual defect you should stop taking Sildenvia and contact your doctor immediately. Cases of visual effects have been reported when using sildenafil.

### Children and adolescents

This medicine should not be given to children or adolescents under the age of 18 years.

### Other medicines and Sildenvia

Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Sildenvia or they may affect how Sildenvia works and this may result in side effects.

Do not use Sildenvia if you take:

- **Nitrate medicines:** Do not take Sildenvia if you are taking nitrate medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) against chest pain (angina pectoris) or heart failure or “poppers” as recreational drugs (nitric oxide donors (such as amyl nitrite), nicorandil or sodium nitroprusside). This is because these substances could lead to a dangerous fall in blood pressure if taken together with Sildenvia.
- **Riociguat:** Do not take Sildenvia if you are taking a medicine called riociguat (or other medicines of a group called guanylate cyclase stimulators). Riociguat is used to treat high blood pressure in the lungs and can lead to a dangerous fall in blood pressure if taken together with Sildenvia .
- **Medicines to treat HIV-infections:** Ritonavir is a medicine used to treat HIV-infections. Do not take Sildenvia if you are taking ritonavir since this combination can lead to a dangerous fall in blood pressure.

Talk to your pharmacist or doctor before using Sildenvia if you are taking:

- **Medicines to treat fungal infections and antibiotics:** Medicines to treat fungal infections called itraconazole or ketoconazole and an antibiotic called erythromycin increase the concentration of Sildenvia in the body and may result in side effects. You should contact your doctor before taking Sildenvia if you are using these medicines.
- **Heartburn treatment:** The medicine to treat heartburn, cimetidine, increases the concentration of Sildenvia in the body and may result in side effects. You should contact your doctor before taking Sildenvia.
- **Other treatments for erectile dysfunction:** The safety and efficacy of combinations of Sildenvia with other treatments for erectile dysfunction have not been studied and this combination is therefore not recommended.
- **Alpha-blockers used to treat urinary problems or high blood pressure:** Alpha-blockers used to treat urinary problems due to enlarged prostate (such as alfuzosin, doxazosin or tamsulosin) may lead to dizziness, lightheadedness, nausea, fainting, lack of concentration, or blurred vision due to low blood pressure (symptomatic hypotension).
- **Medicines containing sacubitril/valsartan, used to treat heart failure:** You should contact your doctor or pharmacist before taking Sildenvia.

### **Sildenvia with food and drink**

Sildenvia can be taken with or without food. When this medicine is taken after a high-fat meal, it may take a little longer to start working.

Do not take Sildenvia with grapefruit or grapefruit juice, because this can affect how the medicine works.

Drinking excessive alcohol can temporarily reduce your ability to achieve an erection. To get a benefit from the medicine, you are advised not to drink large amounts of alcohol before sexual activity.

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

This medicine should not be used by women.

### **Driving and using machines**

Sildenvia can cause dizziness and can affect your vision. Do not drive or use machines if you suffer from these side effects after taking this medicine.

### **Sildenvia contains lactose**

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

### **Sildenvia contains sodium**

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 described in this leaflet or as your pharmacist or doctor have told you. Check with your pharmacist or doctor if you are not sure.

- Take 1 tablet, as needed, approximately 1 hour before sexual activity.
- Swallow the tablet whole with water.
- Do not take more than 1 tablet a day.

Sildenvia will only help you achieve an erection if you are sexually aroused. You and your partner should engage in foreplay just as you would if you were not taking a medicine for erectile dysfunction.

The amount of time this medicine takes to work varies from person to person, but it normally takes between 30 to 60 minutes. You may take it up to 4 hours before sexual activity.

Relax and be patient if Sildenvia does not help you the first time. You can try again later but remember you can only take 1 tablet a day. For most men, Sildenvia will work the first or second time they try it. If it has been some time since you were able to get or keep an erection, it may take a couple of attempts before you achieve the desired effect. Talk to your doctor if you have tried Sildenvia, and are still not able to get and keep an erection. If you feel the effect of Sildenvia is too strong, talk to your pharmacist or doctor.

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

If you take more tablets than recommended, contact your pharmacist or doctor immediately. Taking more than the recommended dose may result in side effects and/or more severe side effects. If you have any further questions on the use of this medicine, ask your pharmacist or doctor.

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

Like all medicines, this medicine can cause side effects although not everybody gets them. These side effects are usually mild to moderate and of a short duration.

Seek medical attention immediately if you experience any of the following serious side effects:

- Chest pains: this occurs uncommonly. If this occurs before, during or after sexual activity: Get in a semi-sitting position and try to relax. Do NOT use nitrates to treat your chest pain.
- A prolonged and sometimes painful erection lasting longer than 4 hours: this occurs rarely.
- A sudden decrease or loss of vision: this occurs rarely.
- An allergic reaction: this occurs uncommonly. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Serious skin reactions such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Syndrome (TEN): this occurs rarely. Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes and 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, indigestion, stuffy nose, dizziness
- facial flushing, hot flush (a sudden feeling of heat in your upper body)
- colour tinge to vision, blurred vision, visual disturbance

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

- vomiting, upper abdominal pain, acid reflux (including heartburn)
- skin rash, pain in the arms or legs, nosebleed, feeling hot, feeling tired (fatigue)
- 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 (typical signs are dizziness, fainting, blurred vision, nausea and tiredness)
- 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 (can be experienced as runny nose, sneezing and stuffy nose)
- presence of blood in urine

**Rare** (may affect up to 1 in 1000 people)

- fainting, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing
- sudden unexpected death caused by loss of heart function (sudden cardiac arrest), stroke, heart attack, chest pains (angina), 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

**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 HPRAs Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie). 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.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton 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 [Invented Name] contains

- The active substance is sildenafil. Each film-coated tablet contains 50 mg of sildenafil (as citrate).
- The other ingredients are:  
Tablet core: microcrystalline cellulose (E460), calcium hydrogen phosphate (anhydrous) (E341), croscarmellose sodium (E468), hypromellose (E464), (see section 2 “Sildenvia contains sodium”) and magnesium stearate (E572).

Film coat: Hypromellose (E464), titanium dioxide (E171), lactose monohydrate (see section 2 “Sildenvia contains lactose”), triacetin (E1518) and indigo carmine aluminium lake (E132).

### What [Invented Name] looks like and contents of the pack

- Sildenvia are blue, almond shaped, approximately 12.5mm in length, 7.5mm in width, biconvex, film-coated tablets, debossed with ‘50’ on one side.
- The tablets are provided in blister packs containing 2, 4 or 8 film-coated tablets within a carton. Not all pack sizes may be marketed.

### Marketing Authorisation Holder

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### This medicine is authorised in the Member States of the EEA under the following names:

Ireland: Sildenvia 50 mg film-coated tablets

**This leaflet was last revised in 11/2023.**