

Package leaflet: Information for the patient

Sildenafil Clonmel 20mg 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

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2. What you need to know before you take Sildenafil Clonmel
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1. What Sildenafil Clonmel is and what it is used for

Sildenafil Clonmel contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

Sildenafil Clonmel brings down blood pressure in the lungs by widening the blood vessels in the lungs.

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

2. What you need to know before you take Sildenafil Clonmel

DO NOT take Sildenafil Clonmel if you:

- are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6)
- 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 Clonmel 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
- 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 have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- have recently had a stroke, a heart attack or if you have severe liver disease or very low blood pressure (< 90/50 mmHg)
- are taking a medicine to treat fungal infections e.g. ketoconazole or itraconazole or medicines containing ritonavir (for HIV)
- have ever had loss of vision because of a problem with blood flow to the nerve in the eye, known as non-arteritic anterior ischaemic optic neuropathy (NAION)

Warnings and precautions

Talk to your doctor before taking Sildenafil Clonmel 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 of the lungs
- have low blood pressure when 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)
- have 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 decline in or loss of vision, **stop taking Sildenafil Clonmel 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 Clonmel 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 Clonmel should not be given to children below 1 year of age.

Other medicines and Sildenafil Clonmel

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. What you need to know before you take Sildenafil Clonmel)
- 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 (a 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)

Sildenafil Clonmel with drink

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

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 Clonmel should not be used during pregnancy unless strictly necessary.

Sildenafil Clonmel should not be given to women of child bearing potential unless using appropriate contraceptive methods.

Stop breast-feeding when you start Sildenafil Clonmel treatment. Sildenafil Clonmel should not be given to women who are breast-feeding since it is not known if the medicine passes into the breast milk.

Driving and using machines

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

Sildenafil Clonmel contains lactose

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

Sildenafil Clonmel contains sodium

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

3. How to take Sildenafil Clonmel

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

Dosage

For adults:

The recommended dose is 20 mg (1 tablet) three times a day

For children and adolescents aged 1 to 17, weighing:

MORE than 20 kg: the recommended dose is 20 mg (1 tablet) three times a day

LESS than 20 kg: the recommended dose is 10 mg three times a day

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 are available for administration to patients weighing less than 20 kg and other younger patients who are not able to swallow tablets.

Method of administration

Leave 6 – 8 hours between doses. Can be taken with or without food.

If you take more Sildenafil Clonmel 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 Clonmel than you should may increase the risk of known side effects.

If you forget to take Sildenafil Clonmel

If you forget to take Sildenafil Clonmel, 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 Clonmel

Suddenly stopping your treatment with Sildenafil Clonmel may lead to your symptoms getting worse. Do not stop taking Sildenafil Clonmel 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, Sildenafil Clonmel can cause side effects, although not everybody gets them.

Most serious side effects:

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

- if you experience sudden decline in 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)

Other side effects

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
- 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
- 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

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
- 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

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

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

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

- nausea
- increased erections
- pneumonia
- runny nose

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sildenafil Clonmel

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 and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

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 Sildenafil Clonmel contains

- The active substance is sildenafil. Each tablet contains 20 mg of sildenafil (as citrate)
- The other ingredients are:
 - Tablet core: lactose monohydrate, microcrystalline cellulose (E460), hydroxypropylcellulose (E463), croscarmellose sodium (E468), silica, colloidal anhydrous (E551), sodium stearyl fumarate (E485)
 - Film coat: Opadry II White (consisting of hypromellose 2910 (E464), titanium dioxide (E171), polydextrose FCC (E1200), talc (E553b), maltodextrin, medium chain triglycerides)

What Sildenafil Clonmel looks like and contents of the pack

Sildenafil Clonmel are round, biconvex, white film-coated tablets with approx. diameter of 7.1 mm and approx. thickness of 3.4 mm.

The product is provided in PVC/PVdC // Al blister packs containing 90 or 300 (3x100) film-coated tablets.

Not all pack sizes may be available.

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC Etten-Leur, The Netherlands

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

DE: Sildenafil AL 20 mg Filmtabletten
FR: SILDENAFIL EG 20 mg, comprimé pelliculé
IE: Sildenafil Clonmel 20 mg film-coated tablets
NL: Sildenafil CF 20 mg, filmomhulde tabletten

SI: Sildenafil STADA 20 mg filmsko obložene tablete

This leaflet was last revised in June 2018.