

Package leaflet: Information for the patient

Silcarfil 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 Silcarfil is and what it is used for
2. What you need to know before you take Silcarfil
3. How to take Silcarfil
4. Possible side effects
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1. What Silcarfil is and what it is used for

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

Silcarfil brings down blood pressure in the lungs by widening the blood vessels in the lungs. Silcarfil 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 Silcarfil

Do not take Silcarfil:

- 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”). Silcarfil 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 Silcarfil 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 Silcarfil 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 Silcarfil 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 Silcarfil 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

Silcarfil should not be given to children below 1 year of age.

Other medicines and Silcarfil

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 Silcarfil).

- 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.

Silcarfil with food and drink

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

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.

Silcarfil should not be used during pregnancy unless strictly necessary.

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

Silcarfil passes into your breast milk at very low levels and would not be expected to harm your baby.

Driving and using machines

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

Silcarfil contains sodium

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

3. How to take Silcarfil

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 10 mg three times a day for children and adolescents ≤ 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 ≤ 20 kg and other younger patients who are not able to swallow tablets.

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

If you forget to take Silcarfil

If you forget to take Silcarfil, 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 Silcarfil

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

If you experience any of the following side effects you should stop taking Silcarfil 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 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 heartbeat, 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 pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRC Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Silcarfil

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.

This medicine 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 Silcarfil contains

- The active substance is sildenafil. Each film-coated tablet contains sildenafil citrate equivalent to 20 mg of sildenafil.
- The other ingredients are:
Tablet Core: Microcrystalline cellulose, calcium hydrogen phosphate anhydrous, croscarmellose sodium, copovidone, magnesium stearate.

Tablet coating: Hypromellose, titanium dioxide (E171), macrogol 4000.

What Silcarfil looks like and contents of the pack

Silcarfil is a white, round (diameter: 7.1 mm), biconvex film-coated tablet with debossment “20” on one side, packed in PVC/Aclar/Aluminium blisters.

Pack sizes: 30, 90, 100, 150, 300 and bundle packs of 300 (2 packs of 150) film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, D-39179 Barleben, Germany.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

AT Sildenafil Sandoz 20 mg - Filmtabletten
BE Balcoga 20 mg filmomhulde tabletten
BG Balcoga
CZ Balcoga
DE Silde - 1A Pharma PAH 20 mg Filmtabletten
ES Balcoga 20 mg comprimidos recubiertos con película EFG
FI Balcoga 20 mg tabletti, kalvopäällysteinen
FR Balcoga 20 mg, comprimé pelliculé
IE Silcarfil 20 mg film-coated tablets
IT Balcoga
LU Balcoga 20 mg comprimés pelliculés
NL Balcoga 20 mg, filmomhulde tabletten
RO Balcoga 20 mg comprimate filmate
SE Balcoga 20 mg filmdragerade tabletter
SI Balcoga 20 mg filmsko obložene tablete
SK Balcoga 20 mg filmom obalené tablet

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