

Package leaflet: Information for the user

Sildenafil Baldacci 50 mg chewable tablets

Sildenafil

Read this leaflet carefully before you start taking this medicine, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
 - If you are not sure, ask your doctor or pharmacist.
 - This medicine has been prescribed for you only. You should not give it to others. The medicine can be harmful to them even if they show the same signs of illness.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist.

What's in this leaflet:

1. What Sildenafil Baldacci is and what it is used for
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1. What Sildenafil Baldacci is and what it is used for

Sildenafil Baldacci contains the active substance sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. This medication works by relaxing the blood vessels in the penis, allowing blood to flow to the penis when sexually stimulated. Sildenafil Baldacci will only help you get an erection if you are sexually stimulated.

Sildenafil Baldacci is a treatment for adult men with erectile dysfunction, more commonly known as impotence. This is when a man is unable to obtain, or maintain, a rigidity of the penis in erection, suitable for sexual activity.

2. Or what do you need to know before taking Sildenafil Baldacci

Do not take Sildenafil Baldacci:

- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination can cause a dangerous drop in your blood pressure. Tell your doctor if you are taking any of these medicines, which are commonly used to relieve angina pectoris (or "chest pain"). If you are not sure, ask your doctor or pharmacist.
- If you are using any of the medicines known as nitric oxide donors, such as amyl nitrite ('poppers'), as the combination could lead to a dangerous drop in your blood pressure.

- 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 due to the presence of clots). The 54 PDE5 inhibitors, such as Viagra, have been shown to increase the hypotensive effects of this drug. If you are taking riociguat or are not sure, talk to your doctor.

- If you have severe heart or liver problems.

- If you have recently had a stroke or myocardial infarction, or if you have low blood pressure.

- If you have certain rare hereditary eye diseases (such as retinitis pigmentosa).

- If you have ever had vision loss due to non-arteritic anterior ischemic optic neuropathy (NAION).

Warnings and precautions

Talk to your doctor or pharmacist before taking Sildenafil Baldacci:

- If you have sickle cell anaemia (an abnormality in red blood cells), leukaemia (cancer of the blood cells), multiple myeloma (cancer of the bone marrow).

- If you have penile deformation or Peyronie's disease.

- If you have heart problems. Your doctor should carefully assess whether your heart can withstand the additional strain associated with sexual intercourse.

- If you currently have a stomach ulcer or bleeding problem (such as hemophilia).

- If you have experienced sudden decrease or loss of vision, stop taking Sildenafil Baldacci and contact your doctor immediately.

You should not use Sildenafil Baldacci at the same time as any other oral or local erectile dysfunction treatments.

You should not use Sildenafil Baldacci concomitantly with pulmonary arterial hypertension (PAH) therapies containing sildenafil or any other PDE5 inhibitors.

You should not take Sildenafil Baldacci if you do not have erectile dysfunction.

You should not take Sildenafil Baldacci if you are a woman.

Special care for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may prescribe you a lower dose.

Children and adolescents

Sildenafil Baldacci should not be administered to individuals under the age of 18 years.

Other medicines and Sildenafil Baldacci

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

Sildenafil Baldacci may interfere with some medicines, especially those used to treat 'chest pain'. In case of a medical emergency, you should tell your doctor, pharmacist or nurse that you are taking Sildenafil Baldacci and when you have done so. Do not take Sildenafil Baldacci with other medicines unless your doctor tells you to do so.

You should not take Sildenafil Baldacci if you are taking medicines called nitrates, as the combination of these medicines can cause a dangerous drop in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines, which are commonly used for the relief of angina pectoris (or "chest pain").

You should not take Sildenafil Baldacci if you are using any of the medicines known as nitric oxide donors, such as amyl nitrite ('poppers'), as the combination may also lead to a dangerous drop in your blood pressure.

If you are already taking riociguat, tell your doctor or pharmacist.

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may want you to start treatment with the lower dose of Sildenafil Baldacci (25 mg).

Some patients who are taking alpha blockers for the treatment of high blood pressure or for enlarged prostate may feel dizzy or faint, which may be caused by low blood pressure when the individual sits or stands up quickly. Some patients have experienced these symptoms when taking Sildenafil Baldacci with alpha blockers. These are most likely to occur within 4 hours of taking Sildenafil Baldacci. To reduce the likelihood of these symptoms occurring, you should be taking a regular daily dose of your alpha blocker before starting treatment with Sildenafil Baldacci. At the start of treatment, your doctor may prescribe the lowest dose of Sildenafil Baldacci (25 mg).

Sildenafil Baldacci with food, drink and alcohol

Sildenafil Baldacci can be taken with or without food. However, you may find that Sildenafil Baldacci may take longer to work if you take it with a heavier meal.

Drinking alcohol can temporarily impede the ability to get an erection. To get the maximum benefit from the medicine, you are advised not to drink large amounts of alcohol before taking Sildenafil Baldacci.

Pregnancy, breastfeeding and fertility Sildenafil Baldacci is not indicated for use by women.

Driving and using machines

Sildenafil Baldacci may cause dizziness and affect vision. You should be aware of how you react to Sildenafil Baldacci before driving or using machines.

Sildenafil Baldacci 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.

Sildenafil Baldacci contains aspartame (E951). Sildenafil Baldacci contains a source of phenylalanine. It may be harmful in individuals with phenylketonuria. Aspartame is a source of phenylalanine. It can be harmful if you have phenylketonuria (PKU), a rare

genetic disorder in which phenylalanine builds up because your body can't remove it properly.

Sildenafil Baldacci contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per tablet, i.e. it is virtually 'sodium-free'.

3. How to take Sildenafil Baldacci

Take this medication exactly as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure. The recommended starting dose is 50 mg. You should not use Sildenafil Baldacci more than once a day.

You should take Sildenafil Baldacci about one hour before your planned time for sexual activity. The tablet should be chewed and then swallowed.

Talk to your doctor or pharmacist if you have the impression that Sildenafil Baldacci is too strong or too weak.

Sildenafil Baldacci will only help you get an erection if you are sexually stimulated. The length of time it takes for Sildenafil Baldacci to work varies from person to person, but typically it ranges from half an hour to an hour. You may find that Sildenafil Baldacci takes longer to work if it is taken with a heavy meal.

If Sildenafil Baldacci does not help you get an erection or if the erection does not last long enough to complete sexual intercourse, you should tell your doctor.

If you take more Sildenafil Baldacci than you should

You may experience an increase in undesirable effects and their severity. Doses greater than 100 mg do not increase efficacy.

You should not take more tablets than your doctor has told you.

If you take more tablets than you should, contact your doctor.

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

4. Possible undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These undesirable effects reported in association with the use of Sildenafil Baldacci are usually mild to moderate and of short duration.

If you experience any of the serious side effects listed below, stop taking Sildenafil Baldacci and seek medical help immediately:

- Allergic reaction – occurs uncommonly (may affect up to 1 in 100 people)
Symptoms include sudden wheezing, difficulty breathing or dizziness, swelling of the eyelids, face, lips, or throat.
- Chest pain – occurs infrequently

If it occurs during or after sex:

- Get into a semi-seated position and try to relax.
- Do not use nitrates to treat your chest pain.

- Prolonged and sometimes painful erections – occurs rarely (may affect up to 1 in 1,000 people)

If you have an erection that lasts continuously for more than 4 hours, you should contact a doctor immediately.

- Sudden decrease or loss of vision – occurs rarely

- Severe skin reactions – occurs rarely

Symptoms may include severe skin peeling and swelling, blisters in the mouth, genitals and around the eyes, fever.

- Seizures or seizures – occurs rarely

Other undesirable effects:

Very common (which may affect more than 1 person in 10): headache.

Common (which may affect up to 1 in 10 people): nausea, facial redness, hot flushing (symptoms include a sudden feeling of warmth in the upper body), indigestion, coloured vision, blurred vision, visual disturbance, stuffy nose and dizziness.

Uncommon (affecting up to 1 person in 100): vomiting, rash, eye irritation, red eyes, eye pain, visual flickering, visual sharpness, sensitivity to light, watery eyes, palpitations, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, drowsiness, decreased sense of touch, dizziness, ringing in the ears, dry mouth, clogged sinuses, inflammation of the lining of the nose (symptoms include a runny nose, sneezing, and stuffy nose), upper abdominal pain, gastroesophageal reflux disease (symptoms include heartburn), presence of blood in the urine, pain in the arms or legs, nosebleeds, feeling hot, and feeling tired.

Rare (which may affect up to 1 person in 1,000): fainting, stroke, heart attack, irregular heartbeat, temporary decrease in blood flow to certain regions of the brain, feeling of tightness in the throat, numb mouth, retinal haemorrhage, double vision, reduced visual acuity, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in vision, vision of halos around lights, dilation of the pupil of the eye, change in the colour of the sclera, bleeding from the penis, presence of blood in the semen, dry nose, swelling of the inside of the nose, irritability and sudden decrease or loss of hearing.

In post-marketing experience, rare cases of unstable angina (heart condition) and sudden death have been reported. It should be noted that most, but not all, men who have experienced these undesirable effects were already suffering from heart problems before taking this drug. It is not possible to determine whether these events were directly related to the administration of VIAGRA.

Reporting of undesirable effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist or nurse. You can also report undesirable

effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>
(preferencialmente)

ou através dos seguintes contactos:

Direção de Gestão do Risco de Medicamentos

Parque da Saúde de Lisboa, Av. Brasil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Linha do Medicamento: 800222444 (gratuita)

E-mail: farmacovigilancia@infarmed.pt

5. How to store Sildenafil Baldacci

Store in the original packaging to protect from light.

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. The expiry date corresponds to the last day of the month indicated.

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

6. Package contents and other information

What Sildenafil Baldacci contains

- The active substance is sildenafil. Each chewable tablet contains 50 mg of sildenafil formed in situ from 70.24 mg of sildenafil citrate.

- The other ingredients are: potassium polyacryline, magnesium stearate, colloidal anhydrous silica, aspartame, croscarmellose sodium, peppermint flavouring, lactose monohydrate and povidone K 30.

What Sildenafil Baldacci looks like and contents of the pack

Sildenafil Baldacci 50 mg chewable tablets are white, triangular, biconvex tablets debossed with "50" on one side.

The tablets are supplied in PVC/PCTFE-Alu blister packs containing 1, 2, 4, 8 and 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

Baldacci - Portugal, S.A.

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1549-005 Lisboa

Portugal

Maker

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Greece

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KW20A Kordin Industrial
Park, Paola, PLA 3000
Malta

This leaflet was last revised in November 2021