

PACKAGE LEAFLET: Information for the user

BLUAGRA

Film-coated tablets – 50 mg, 100 mg

(Sildenafil citrate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Bluagra is and what it is used for
2. Before you take Bluagra
3. How to take Bluagra
4. Possible side effects
5. How to store Bluagra
6. Further information

1. WHAT BLUAGRA IS AND WHAT IT IS USED FOR

Bluagra contains the active substance sildenafil. Sildenafil belongs to a group of medicines called **phosphodiesterase type 5 (PDE) inhibitors**. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get **sexually excited**.

Bluagra will only help you to get an erection if you are **sexually stimulated**.

You should not take Bluagra if you do not have erectile dysfunction. You should not take Bluagra if you are a **woman**.

Bluagra is a treatment for men with erectile dysfunction, sometimes known as **impotence**. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

2. BEFORE YOU TAKE BLUAGRA

Do not take Bluagra:

- if you have ever had an **allergic** reaction to sildenafil or to any of the excipients of the tablet; an allergic reaction can be a rash, itching, a swollen face, swollen lips or shortness of breath. If this has ever happened to you, tell your doctor;
- if you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrite; these medicines are often given for relief of angina pectoris (**or "chest pain"**); Bluagra 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 have a severe heart or liver problem;
- if you have **recently** had a stroke or a heart attack, or if you have low blood pressure;
- if you have certain rare inherited eye diseases (**such as retinitis pigmentosa**);
- **if you have ever had loss of vision because of non-arteritic anterior ischaemic optic neuropathy (NAION).**

Take special care with Bluagra

Please tell your doctor:

- if you have sickle cell anaemia (**an abnormality of red blood cells**), leukaemia (**cancer of blood cells**), multiple myeloma (**cancer of bone marrow**);
- if you have a Peyronie's disease or deformity of your penis; these conditions may require special care when taking medicines for erectile dysfunction;
- if you have problems with your heart; in that case your doctor should carefully check whether your heart can take the **additional** strain of having sex;
- if you currently have a stomach ulcer, or a bleeding disorder (**such as haemophilia**);
- **if you experience sudden decrease or loss of vision, stop taking Bluagra and contact your doctor.**

You should **not** use Bluagra with any **other** treatment for erectile dysfunction.

Special considerations for children and adolescents

Bluagra should not be given to **individuals** under the age of **18**.

Elderly patients over 65 years of age

The first dose should be adjusted to the lowest one.

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide if your dose should be **adjusted**.

Taking other medicines

Other concomitant drug treatment may affect or be affected by Bluagra.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Remember to tell your doctor about the Bluagra treatment if you are prescribed another drug during treatment.

Bluagra tablets may **interfere** with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell anyone treating your condition that you have taken Bluagra. Do not take Bluagra with other medicines unless your doctor tells you that you can.

Bluagra may cause a serious **increase** in the effects of medicines called nitrates, and nitric oxide donors such as amyl nitrite. These are often used for the relief of angina pectoris (or "chest pain"). You should not take Bluagra if you are taking these medicines.

If you are taking **protease inhibitors**, such as for the treatment of HIV, your doctor may start you on the lowest dose (**25 mg**) of sildenafil.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking sildenafil with alpha-blockers. This is most likely to occur within 4 hours after taking sildenafil. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start Bluagra. Your doctor may start you a lower dose (25 mg) of sildenafil.

Taking Bluagra with food and drinks

Bluagra can be taken with or without food. However, you may find that sildenafil takes longer to

start working if you take it with a heavy meal.

Drinking **alcohol** can temporarily impair the ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink large amounts of alcohol before taking Bluagra.

Pregnancy and breastfeeding

Bluagra is not **indicated** for women.

Driving and using machines

Bluagra can cause dizziness and effects on vision. You should be **aware** of how you react to Bluagra before you drive or operate machinery.

Important information about some of the excipients of Bluagra

This medicinal product contains the azo dye FD&C Red #40. This ingredient may cause allergic reactions.

3. HOW TO TAKE BLUAGRA

Always take Bluagra exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual starting dose of sildenafil is 50 mg.

You should not take Bluagra more than once daily.

You should take Bluagra about **one hour** before sexual activity. Swallow the tablet **whole** with some water.

If you have the **impression** that the effect of Bluagra is too strong or too weak, tell your doctor or pharmacist.

Bluagra will only help you to get an erection if you are **sexually stimulated**. It will not give you an erection if you are not sexually stimulated. The time Bluagra takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Bluagra takes longer to work if you take it with a heavy meal.

If Bluagra does not help you to get an erection or if your erection does not last long **enough** for

you to complete **sexual intercourse** you should tell your doctor.

If you take more Bluagra than you should

If you take more Bluagra than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on the actions to be taken.

A dose above **100 mg** does not increase the efficacy. However, it will **result** in an increase in undesirable effects and their severity.

You should not take more tablets than your doctor tells you to.

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

4. POSSIBLE SIDE EFFECTS

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

The side effects reported in association with the use of Bluagra are usually mild to moderate and of a short duration.

If you have **chest pain** during or after intercourse:

- get in a semi-sitting position and try to relax;
- do not use nitrates to treat your chest pain;
- contact your doctor immediately.

All medicines, including Bluagra, can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking Bluagra: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking sildenafil. If you have such an erection which may last for more than **4 hours**, you should contact a doctor immediately.

If you experience a sudden decrease or loss of vision, stop taking Bluagra and contact your doctor immediately.

The frequency of possible side effects is shown in the table below:

Very common:	occur in more than 1 in 10 users
Common:	occur in less than 1 in 10, but more than 1 in 100 users
Uncommon:	occur in less than 1 in 100 users but more than 1 in 1.000 users
Rare:	occur in less than 1 in 1.000, but more than 1 in 10.000 users
Very rare:	occur in less than 1 in 10.000 users, including isolated cases

Very common side effects: headache

Common side effects:

- facial flushing
- indigestion
- dizziness
- stuffy nose
- effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision)
- hair loss (alopecia)
- anaemia
- anxiety
- cough
- diarrhoea
- fluid retention
- gastrointestinal discomfort
- gastrointestinal disorders
- increased risk of infection
- insomnia
- nausea
- night sweats
- pain
- tremor.

Uncommon side effects:

- vomiting
- skin rash
- bleeding at the back of the eye
- bloodshot eyes / red eyes
- eyes pain

- abnormal sensation in the eye
- dry eye
- irregular or rapid heartbeat
- muscle pain
- feeling sleepy
- reduced sense of touch
- vertigo
- ringing in the ears
- dry mouth
- chest pain
- feeling tired
- feeling hot
- gynaecomastia
- haemorrhage
- hypertension
- hypotension
- numbness
- sinus congestion.

Rare side effects:

- sudden decrease or loss of hearing
- fainting
- nosebleed
- acute coronary syndrome
- arteriosclerotic retinopathy
- cerebrovascular insufficiency
- glaucoma
- haematospermia
- irritability
- optic neuropathy
- oral hypoesthesia

- priapism
- retinal occlusion
- scleral discolouration
- severe cutaneous adverse reactions (SCARs)
- sudden cardiac death
- throat tightness.

Very rare side effects:

- convulsions or seizures.

Additional side effects reported from post-marketing experience include: pounding heartbeat, heart attack.

Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to sildenafil. Cases of convulsions or seizures have also been reported.

If any of the side effects gets serious, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BLUAGRA

Keep out of the reach and sight of children.

Do not use Bluagra after the expiry date which is stated on the package.

Do not store above 25 °C.

Store in the original package in order to protect from light and humidity.

6. FURTHER INFORMATION

What Bluagra 50 mg film-coated tablets contain

The **active substance** is sildenafil citrate.

One film-coated tablet Bluagra 50 mg contains 70.24 mg sildenafil citrate equivalent to 50 mg sildenafil.

The **excipients** are:

Tablet core: microcrystalline cellulose, magnesium stearate, croscarmellose sodium, povidone,

pregelatinised starch.

Film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, indigo carmine, FD&C Red #40, black iron oxide.

What Bluagra 100 mg film-coated tablets contain

The **active substance** is sildenafil citrate.

One film-coated tablet Bluagra 100 mg contains 140.48 mg sildenafil citrate equivalent to 100 mg sildenafil.

The **excipients** are:

Tablet core: microcrystalline cellulose, magnesium stearate, croscarmellose sodium, povidone, pregelatinised starch.

Film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, indigo carmine, FD&C Red #40, black iron oxide.

Contents of the pack

Bluagra 50 mg: box with 4 film-coated tablets.

Bluagra 100 mg: box with 3 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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