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VIAGRA Generic (sildenafil citrate) Tablets DESCRIPTION

VIAGRA Generic, an oral therapy for erectile dysfunction, is the citrate salt of sildenafil, a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5).

Sildenafil citrate is designated chemically as 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate.

Generic VIAGRA (sildenafil citrate) is formulated as blue, film-coated rounded-diamond-shaped tablets equivalent to 25 mg, 50 mg and 100 mg of sildenafil for oral administration. In addition to the active ingredient, sildenafil citrate, each tablet contains the following inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide, lactose, triacetin, and FD & C Blue #2 aluminum lake.

CLINICAL PHARMACOLOGY

Mechanism of Action

The physiologic mechanism of erection of the penis involves release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. NO then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (cGMP), producing smooth muscle relaxation in the corpus cavernosum and allowing inflow of blood. Sildenafil has no direct relaxant effect on isolated human corpus cavernosum, but enhances the effect of nitric oxide (NO) by inhibiting phosphodiesterase type 5 (PDE5), which is responsible for degradation of cGMP in the corpus cavernosum. When sexual stimulation causes local release of NO, inhibition of PDE5 by sildenafil causes increased levels of cGMP in the corpus cavernosum, resulting in smooth muscle relaxation and inflow of blood to the corpus cavernosum. Sildenafil at recommended doses has no effect in the absence of sexual stimulation.

PATIENT SUMMARY OF INFORMATION ABOUT

Generic VIAGRA (sildenafil citrate) tablets

This summary contains important information about Generic VIAGRA. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking VIAGRA Generic. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about Generic VIAGRA.

This medicine can help many men when it is used as prescribed by their doctors. However, VIAGRA Generic is not for everyone. It is intended for use only by men who have a condition called erectile dysfunction. Generic VIAGRA must never be used by men who are taking medicines that contain nitrates of any kind, at any time. This includes nitroglycerin. If you take Generic VIAGRA

with any nitrate medicine your blood pressure could suddenly drop to an unsafe or life threatening level.

• WHAT IS Generic VIAGRA?

Generic VIAGRA is a pill used to treat erectile dysfunction (impotence) in men. It can help many men

who have erectile dysfunction get and keep an erection when they become sexually excited (stimulated).

You will not get an erection just by taking this medicine. VIAGRA helps a man with erectile dysfunction get an erection only when he is sexually excited.

- HOW SEX AFFECTS THE BODY

When a man is sexually excited, the penis rapidly fills with more blood than usual. The penis then expands and hardens. This is called an erection. After the man is done having sex, this extra blood flows out of the penis back into the body. The erection goes away.

If an erection lasts for a long time (more than 6 hours), it can permanently damage your penis. You should call a doctor immediately if you ever have a prolonged erection that lasts more than 4 hours.

Some conditions and medicines interfere with this natural erection process. The penis cannot fill with enough blood. The man cannot have an erection. This is called erectile dysfunction if it becomes a frequent problem.

During sex, your heart works harder. Therefore sexual activity may not be advisable for people who have heart problems. Before you start any treatment for erectile dysfunction, ask your doctor if your heart is healthy enough to handle the extra strain of having sex. If you have chest pains, dizziness or nausea during sex, stop having sex and immediately tell your doctor you have had this problem.

- HOW Generic VIAGRA WORKS

VIAGRA Generic enables many men with erectile dysfunction to respond to sexual stimulation. When a man is sexually excited, VIAGRA Generic helps the penis fill with enough blood to cause an erection. After sex is over, the erection goes away.

- VIAGRA IS NOT FOR EVERYONE

As noted above (How Sex Affects the Body), ask your doctor if your heart is healthy enough for sexual activity.

If you take any medicines that contain nitrates – either regularly or as needed – you should never take VIAGRA Generic. If you take Generic VIAGRA with any nitrate medicine or recreational drug containing nitrates, your blood pressure could suddenly drop to an unsafe level. You could get dizzy, faint, or even have a heart attack or stroke. Nitrates are found in many prescription medicines that are used to treat angina (chest pain due to heart disease) such as:

- nitroglycerin (sprays, ointments, skin patches or pastes, and tablets that are swallowed or dissolved in the mouth)

isosorbide mononitrate and isosorbide dinitrate (tablets that are swallowed, chewed, or dissolved in the mouth)

. Nitrates are also found in recreational drugs such as amyl nitrate or nitrite (“poppers”). If you are not sure if any of your medicines contain nitrates, or if you do not understand what nitrates are, ask your doctor or pharmacist.

Generic VIAGRA is only for patients with erectile dysfunction. VIAGRA Generic is not for newborns, children, or women. Do not let anyone else take your VIAGRA. VIAGRA must be used only under a doctor’s supervision.

- WHAT Generic VIAGRA DOES NOT DO

- Generic VIAGRA does not cure erectile dysfunction. It is a treatment for erectile dysfunction.
- Generic VIAGRA does not protect you or your partner from getting sexually transmitted diseases, including HIV—the virus that causes AIDS.
- Generic VIAGRA is not a hormone or an aphrodisiac.

- WHAT TO TELL YOUR DOCTOR BEFORE YOU BEGIN VIAGRA Generic

Only your doctor can decide if VIAGRA is right for you. VIAGRA can cause mild, temporary lowering of your blood pressure. You will need to have a thorough medical exam to diagnose your erectile dysfunction and to find out if you can safely take VIAGRA alone or with your other medicines. Your doctor should determine if your heart is healthy enough to handle the extra strain of having sex.

Be sure to tell your doctor if you:

- have ever had any heart problems (e.g., angina, chest pain, heart failure, irregular heart beats, heart attack or narrowing of the aortic valve)
- have ever had a stroke
- have low or high blood pressure
- have ever had severe vision loss
- have a rare inherited eye disease called retinitis pigmentosa
- have ever had any kidney problems
- have ever had any liver problems
- have ever had any blood problems, including sickle cell anemia or leukemia
- are allergic to sildenafil or any of the other ingredients of VIAGRA tablets
- have a deformed penis, Peyronie's disease, or ever had an erection that lasted more than 4 hours
- have stomach ulcers or any types of bleeding problems
- are taking any other medicines

- **Generic VIAGRA AND OTHER MEDICINES**

Some medicines can change the way Generic VIAGRA works. Tell your doctor about any medicines you are taking. Do not start or stop taking any medicines before checking with your doctor or pharmacist. This includes prescription and nonprescription medicines or remedies:

- Remember, VIAGRA should never be used with medicines that contain nitrates (see Generic VIAGRA Is Not for Everyone).
- If you are taking medicines called alpha-blockers for the treatment of high blood pressure or prostate problems, your blood pressure could suddenly drop. You could get dizzy or faint.
- If you are taking a protease inhibitor, your dose may be adjusted (please see Finding the Right Dose for You).
- VIAGRA should not be used with any other medical treatments that cause erections. These treatments include pills, medicines that are injected or inserted into the penis, implants or vacuum pumps.
- VIAGRA contains sildenafil, which is the same medicine found in another drug called REVATIO. REVATIO is used to treat a rare disease called pulmonary arterial hypertension. VIAGRA should not be used with REVATIO.

- **FINDING THE RIGHT DOSE FOR YOU**

VIAGRA Generic comes in different doses (25 mg, 50 mg and 100 mg). If you do not get the results you expect, talk with your doctor. You and your doctor can determine the dose that works best for you.

- Do not take more Generic VIAGRA than your doctor prescribes.

If you think you need a larger dose of VIAGRA, check with your doctor.

VIAGRA should not be taken more than once a day.

Your doctor may prescribe a lower dose of VIAGRA in certain circumstances. For example:

- If you are older than age 65, or have serious liver or kidney problems, your doctor may start you at the lowest dose (25 mg) of Generic VIAGRA. If you are taking protease inhibitors, such as for the treatment of HIV, your doctor may recommend a 25 mg dose and may limit you to a maximum single dose of 25 mg of VIAGRA in a 48 hour period.

If you have prostate problems or high blood pressure for which you take medicines called alpha blockers, your doctor may start you on a lower dose of

VIAGRA.

- HOW TO TAKE VIAGRA Generic

Take VIAGRA about one hour before you plan to have sex. Beginning in about 30 minutes and for up to 4 hours, VIAGRA can help you get an erection if you are sexually excited. If you take Generic VIAGRA after a high-fat meal (such as a cheeseburger and french fries), the medicine may take a little longer to start working. VIAGRA can help you get an erection when you are sexually excited. You will not get an erection just by taking the pill.

- POSSIBLE SIDE EFFECTS

Like all medicines, VIAGRA Generic can cause some side effects. These effects are usually mild to moderate and usually don't last longer than a few hours. Some of these side effects are more likely to occur with higher doses.

The most common side effects of Generic VIAGRA are headache, flushing of the face, and upset stomach. Less common side effects that may occur are temporary changes in color vision (such as trouble telling the difference between blue and green objects or having a blue color tinge to them), eyes being more sensitive to light, or blurred vision.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including Generic VIAGRA) reported a sudden decrease or loss of vision in one or both eyes. It is not possible to determine whether these events are related directly to these medicines, to other factors such as high blood pressure or diabetes, or to a combination of these. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including Generic VIAGRA, and call a doctor right away.

In rare instances, men have reported an erection that lasts many hours. You should call a doctor immediately if you ever have an erection that lasts more than 4 hours. If not treated right away, permanent damage to your penis could occur (see How Sex Affects the Body). Sudden loss or decrease in hearing, sometimes with ringing in the ears and dizziness, has been rarely reported in people taking PDE5 inhibitors, including Generic VIAGRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors, to other diseases or medications, to other factors, or to a combination of factors. If you experience these symptoms, stop taking VIAGRA and contact a doctor right away.

Heart attack, stroke, irregular heart beats, and death have been reported rarely in men taking Generic VIAGRA. 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 Generic VIAGRA.

VIAGRA Generic may cause other side effects besides those listed on this sheet. If you want more information or develop any side effects or symptoms you are concerned about, call your doctor.

- ACCIDENTAL OVERDOSE

In case of accidental overdose, call your doctor right away.

- STORING Generic VIAGRA

Keep VIAGRA out of the reach of children. Keep VIAGRA in its original container. Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).