# BACK

activity, to the patient's underlying cardiovascular disease, to a combination of these factors, or to other factors.

**Hemic and Lymphatic:**
Vaso-occlusive crisis: In a small, prematurely terminated study of sildenafil in patients with pulmonary arterial hypertension (PAH) secondary to sickle cell disease, vaso-occlusive crises requiring hospitalization were more commonly reported in patients who received sildenafil than in those randomized to placebo. The clinical relevance of this finding to men treated with sildenafil for ED is not known.

**Nervous:** seizure, seizure recurrence, anxiety, and transient global amnesia.

**Respiratory:** epistaxis

**Special senses:**

***Hearing:*** Cases of sudden decrease or loss of hearing have been reported postmarketing in temporal association with the use of PDE5 inhibitors, including sildenafil. In some of the cases, medical conditions and other factors were reported that may have also played a role in the otologic adverse events. In many cases, medical follow-up information was limited. It is not possible to determine whether these reported events are related directly to the use of sildenafil, to the patient's underlying risk factors for hearing loss, a combination of these factors, or to other factors.

***Ocular*:** diplopia, temporary vision loss/decreased vision, ocular redness or bloodshot appearance, ocular burning, ocular swelling/pressure, increased intraocular pressure, retinal edema, retinal vascular disease or bleeding, and vitreous traction /detachment.

Non-arteritic anterior ischemic optic neuropathy (NAION), a cause of decreased vision including permanent loss of vision, has been reported rarely post-marketing in temporal association with the use of phosphodiesterase type 5 (PDE5) inhibitors, including sildenafil.

Most, but not all, of these patients had underlying anatomic or vascular risk factors for developing NAION, including but not necessarily limited to: low cup to disc ratio ("crowded disc"), age over 50, diabetes, hypertension, coronary artery disease, hyperlipidemia and smoking.

**Urogenital:**
Prolonged erection, priapism

**OVERDOSE**
In published studies with healthy volunteers of single doses up to 800 mg, adverse reactions were similar to those seen at lower doses but incidence rates and severities were increased.

In cases of overdose, standard supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as sildenafil is highly bound to plasma proteins and it is not eliminated in the urine.

**PHARMACOLOGICAL PROPERTIES**

**PHARMACODYNAMIC**

Pharmacotherapeutic group: Genito Urinary System and Sex Hormones, Urologicals; Drugs used in erectile dysfunction, ATC Code: G04B E03.

**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 enhances the effect of NO by inhibiting phosphodiesterase type 5 (PDE5), which is responsible for degradation of cGMP in the corpus cavernosum. Sildenafil has no direct relaxant effect on isolated human 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.

In addition to human corpus cavernosum smooth muscle, PDE5 is also found in other tissues including platelets, vascular and visceral smooth muscle, and skeletal muscle, brain, heart, liver, kidney, lung, pancreas, prostate, bladder, testis, and seminal vesicle. The inhibition of PDE5 in some of these tissues by sildenafil may be the basis for the enhanced platelet antiaggregatory activity of NO observed *in vitro*, an inhibition of platelet thrombus formation *in vivo* and peripheral arterial-venous dilatation *in vivo*.

**PHARMACOKINETIC**
Sildenafil is rapidly absorbed after oral administration, with a mean absolute bioavailability of 41% (range 25- 63%). The pharmacokinetics of sildenafil are dose-proportional over the recommended dose range. It is eliminated predominantly by hepatic metabolism (mainly CYP3A4) and is converted to an active metabolite with properties similar to the parent, sildenafil. Both sildenafil and the metabolite have terminal half-lives of about 4 hours.

**Absorption & Distribution**
Sildenafil is rapidly absorbed. Maximum observed plasma concentrations are reached within 30 to 120 minutes (median 60 minutes) of oral dosing in the fasted state. When Sildenafil is taken with a high fat meal, the rate of absorption is reduced, with a mean delay in Tmax of 60 minutes and a mean reduction in Cmax of 29%. The mean steady state volume of distribution (Vss) for sildenafil is 105 L, indicating distribution into the tissues. Sildenafil and its major circulating N-desmethyl metabolite are both approximately 96% bound to plasma proteins. Protein binding is independent of total drug concentrations.

Based upon measurements of sildenafil in semen of healthy volunteers 90 minutes after dosing, less than 0.001% of the administered dose may appear in the semen of patients.

**Metabolism & Excretion**
Sildenafil is cleared predominantly by the CYP3A4 (major route) and CYP2C9 (minor route) hepatic microsomal isoenzymes. The major circulating metabolite results from N-desmethylation of sildenafil, and is itself further metabolized. This metabolite has a PDE selectivity profile similar to sildenafil and an *in vitro* potency for PDE5 approximately 50% of the parent drug. Plasma concentrations of this metabolite are approximately 40% of those seen for sildenafil, so that the metabolite accounts for about 20% of sildenafil's pharmacologic effects.

After either oral or intravenous administration, sildenafil is excreted as metabolites predominantly in the feces (approximately 80% of administered oral dose) and to a lesser extent in the urine (approximately 13% of the administered oral dose). Similar values for pharmacokinetic parameters were seen in normal volunteers and in the patient population, using a population pharmacokinetic approach.

**PRECLINICAL SAFETY DATA**

Carcinogenesis
Sildenafil was not carcinogenic when administered to rats for 24 months at a dose resulting in total systemic drug exposure (AUCs) for unbound sildenafil and its major metabolite of 20- and 38-times, for male and female rats, respectively, the exposures observed in human males given the Maximum Recommended Human Dose (MRHD) of 100 mg. Sildenafil was not carcinogenic when administered to mice for 18-21 months at dosages up to the Maximum Tolerated Dose (MTD) of 10 mg/kg/day, approximately 0.4 times the MRHD on a mg/m$^2$ basis in a 50 kg subject.

Mutagenesis
Sildenafil was negative in in vitro bacterial and Chinese hamster ovary cell assays to detect mutagenicity, and in vitro human lymphocytes and in vivo mouse micronucleus assays to detect clastogenicity.

Impairment of Fertility
There was no impairment of fertility in rats given sildenafil up to 60 mg/kg/day for 36 days to females and 102 days to males, a dose producing an AUC value of more than 25 times the human male AUC.

**PHARMACEUTICAL PARTICULARS**
**INCOMPATIBILITY**
Not applicable.

**SHELF LIFE**
36 months

**STORAGE CONDITION**
Store at a temperature below 30°C. Protect from light.

**NATURE AND CONTENTS OF CONTAINER**
4 Tablets in a Blister Pack in a Printed Carton along with Package Insert.

**MANUFACTURING AUTHORISATON HOLDER AND MANUFACTURER**

| Manufacturing Authorization Holder | Manufacturer |
|---|---|
| Ajanta Pharma Limited<br>Ajanta House, Charkop<br>Kandivli (West)<br>Mumbai - 400 067, India.<br>Tel : 022-6913 2111/2112<br>Fax : 022-6913 2070<br>Email :<br>info@ajantapharma.com | Ajanta Pharma Limited<br>B-4-5-6, MIDC Industrial Area<br>Paithan, Aurangabad, 431148<br>Dist: Aurangabad<br>Maharashtra, India.<br>Tel : +91-2431-664000<br>Fax : +91-2431-664100 |

**Last Revision Date:** Aug 18, 2023

# KAMAGRA

## Sildenafil Citrate Tablets

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet?**


**1. What KAMAGRA is and what it is used for**
KAMAGRA is a prescription medicine used to treat erectile dysfunction (ED). You will not get an erection just by taking this medicine. KAMAGRA helps a man with erectile dysfunction get and keep an erection only when he is sexually excited (stimulated).

KAMAGRA is not for use in women or children.

It is not known if KAMAGRA is safe and effective in women or children under 18 years of age.

**2. What you need to know before you use Kamagra**
KAMAGRA can cause your blood pressure to drop suddenly to an unsafe level if it is taken with certain other medicines. Do not take KAMAGRA if you take any other medicines called "nitrates." Nitrates are used to treat chest pain (angina). A sudden drop in blood pressure can cause you to feel dizzy, faint, or have a heart attack or stroke.

Do not take KAMAGRA if you take medicines called guanylate cyclase stimulators which include:

Riociguat a medicine that treats pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension.

Tell all your healthcare providers that you take KAMAGRA.

If you need emergency medical care for a heart problem, it will be important for your healthcare provider to know when you last took KAMAGRA.

Stop sexual activity and get medical help right away if you get symptoms such as chest pain, dizziness, or nausea during sex.

Sexual activity can put an extra strain on your heart, especially if your heart is already weak from a heart attack or heart disease. Ask your doctor if your heart is healthy enough to handle the extra strain of having sex.

KAMAGRA does not protect you or your partner from getting sexually transmitted diseases, including HIV—the virus that causes AIDS.

Do not take KAMAGRA if you:
- take medicines called nitrates (such as nitroglycerin)
- use street drugs called "poppers" such as amyl nitrate or amyl nitrite, and butyl nitrate
- take any medicines called guanylate cyclase stimulators such as riociguat.
- are allergic to sildenafil, as contained in KAMAGRA and REVATIO, or any of the ingredients in KAMAGRA. See the end of this leaflet for a complete list of ingredients in KAMAGRA.

**Before you take KAMAGRA, tell your healthcare provider if you:**
- have or have had heart problems such as a heart attack, irregular heartbeat, angina, chest pain, narrowing of the aortic valve or heart failure
- have had heart surgery within the last 6 months
- have pulmonary hypertension
- have had a stroke
- have low blood pressure, or high blood pressure that is not controlled
- have a deformed penis shape
- have had an erection that lasted for more than 4 hours
- have problems with your blood cells such as sickle cell anemia, multiple myeloma, or leukemia
- have retinitis pigmentosa, a rare genetic (runs in families) eye disease
- have ever had severe vision loss, including an eye problem called non-arteritic anterior ischemic optic neuropathy (NAION)
- have bleeding problems
- have or have had stomach ulcers
- have liver problems
- have kidney problems or are having kidney dialysis
- have any other medical conditions

**Tell your healthcare provider about all the medicines you take*,**
Including prescription and over-the-counter medicines, vitamins, and herbal supplements.
KAMAGRA may affect the way other medicines work, and other medicines may affect the way KAMAGRA works causing side effects. Especially tell your healthcare provider if you take any of the following:
- Medicines called nitrates (see "What is the most important information I should know about KAMAGRA?")
- medicines called guanylate cyclase stimulators, such as riociguat.
- Medicines called alpha blockers such as terazosin, tamsulosin, doxazosin, prazosin, alfuzosin, dutasteride and tamsulosin, or silodosin. Alpha-blockers are sometimes prescribed for prostate problems or high blood pressure. In some patients, the use of KAMAGRA with alpha-blockers can lead to a drop in blood pressure or to fainting.
- medicines called HIV protease inhibitors, such as ritonavir, indinavir sulfate, saquinavir or atazanavir sulfate.
- some types of oral antifungal medicines, such as ketoconazole, and itraconazole.
- some types of antibiotics, such as clarithromycin, telithromycin, or erythromycin
- other medicines that treat high blood pressure
- other medicines or treatments for ED
- KAMAGRA contains sildenafil, KAMAGRA should not be used with other pulmonary arterial hypertension (PAH) treatments containing sildenafil or any other PDE5 inhibitors (such as tadalafil).

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.
Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

**3. How to use KAMAGRA**
- Take KAMAGRA exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much KAMAGRA to take and when to take it.
- Your healthcare provider may change your dose if needed.
- Take KAMAGRA about 1 hour before sexual activity. You may take KAMAGRA between 30 minutes to 4 hours before sexual activity if needed.
- KAMAGRA can be taken with or without food. If you take KAMAGRA after a high fat meal (such as a cheeseburger and french fries), KAMAGRA may take a little longer to start working
- **Do not** take KAMAGRA more than 1 time a day.

If you accidentally take too much KAMAGRA, call your doctor or go to the nearest hospital emergency room right away

**4. Possible side effects**
**KAMAGRA can cause serious side effects**. Rarely reported side effects include:
- **An erection that will not go away (priapism).** If you have an erection that lasts more than 4 hours, get medical help right away. If it is not treated right away, priapism can permanently damage your penis.
- **Sudden vision loss in one or both eyes.** Sudden vision loss in one or both eyes can be a sign of a serious eye problem called non-arteritic anterior ischemic optic neuropathy (NAION). It is uncertain whether PDE5 inhibitors directly cause the vision loss. Stop taking KAMAGRA and call your healthcare provider right away if you have sudden vision loss in one or both eyes.
- **Sudden hearing decrease or hearing loss.** Some people may also have ringing in their ears (tinnitus) or dizziness. If you have these symptoms, stop taking KAMAGRA and contact a doctor right away.

**The most common side effects of KAMAGRA are:**
- headache
- flushing
- upset stomach
- abnormal vision, such as changes in color vision (such as having a blue color tinge) and blurred vision
- stuffy or runny nose
- back pain
- muscle pain
- nausea
- dizziness
- rash

In addition, heart attack, stroke, irregular heartbeats and death have happened rarely in men taking KAMAGRA. Most, but not all, of these men had heart problems before taking KAMAGRA. It is not known if KAMAGRA caused these problems.

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of KAMAGRA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects.

**5. How to store KAMAGRA**

Keep this medicine out of the sight and reach of children.

Store at a temperature below 30°C. Protect from light.

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.

**6. Contents of the pack and other information**
**What KAMAGRA contains:**

**Kamagra 50 (Sildenafil Citrate Tablets 50 mg)**
Each film coated tablet contains:
Sildenafil Citrate
equivalent to Sildenafil 50 mg

**Kamagra 100 (Sildenafil Citrate Tablets 100 mg)**
Each film coated tablet contains:
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equivalent to Sildenafil 100 mg

**List of Excipients:**
Sodium Starch Glycolate (Type A), Povidone, Isopropyl Alcohol, Microcrystalline Cellulose, Purified Talc, Magnesium Stearate, Insta Moistshield Aqua II A22D20470 Green and Purified Water.

**What KAMAGRA looks like and contents of the pack**
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