

# BACK

General disorders and administration site conditions			Chest pain, Fatigue, Feeling hot	Irritability
Investigations			Heart rate increased	

\*Reported during post-marketing surveillance only \*\*Visual colour distortions: Chloropsia, Chromatopsia, Cyanopsia, Erythropsia and Xanthopsia  
\*\*\*Lacrimation disorders: Dry eye, lacrimal disorder and Lacrimation increased).

## OVERDOSE

In single dose volunteer studies of doses up to 800 mg, adverse reactions were similar to those seen at lower doses, but the incidence rates and severities were increased. Doses of 200 mg did not result in increased efficacy but the incidence of adverse reactions (headache, flushing, dizziness, dyspepsia, nasal congestion, altered vision) was 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 not eliminated in the urine.

## PHARMACOLOGICAL PROPERTIES

### PHARMACODYNAMIC

Pharmacotherapeutic group: Urologicals; Drugs used in erectile dysfunction.  
ATC Code: G04B E03

Mechanism of action Sildenafil is an oral therapy for erectile dysfunction. In the natural setting, i.e. with sexual stimulation, it restores impaired erection function by increasing blood flow to the penis. The physiological mechanism responsible for erection of the penis involves the release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. Nitric oxide 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 is a potent and selective inhibitor of cGMP specific phosphodiesterase type 5 (PDE5) in the corpus cavernosum, where PDE5 is responsible for degradation of cGMP. Sildenafil has a peripheral site of action on erections. Sildenafil has no direct relaxant effect on isolated human corpus cavernosum but potentially enhances the relaxant effect of NO on this tissue. When the NO/cGMP pathway is activated, as occurs with sexual stimulation, inhibition of PDE5 by sildenafil results in increased corpus cavernosum levels of cGMP. Therefore sexual stimulation is required in order for sildenafil to produce its intended beneficial pharmacological effects.

## PHARMACOKINETIC

### Absorption

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. The mean absolute oral bioavailability is 41% (range 25-63%). After oral dosing of sildenafil AUC and Cmax increase in proportion with dose over the recommended dose range (25-100 mg). When sildenafil is taken with food, the rate of absorption is reduced with a mean delay in tmax of 60 minutes and a mean reduction in Cmax of 29%.

### Distribution

The mean steady state volume of distribution (Vd) for sildenafil is 105 l, indicating distribution into the tissues. After a single oral dose of 100 mg, the mean maximum total plasma concentration of sildenafil is approximately 440 ng/mL (CV 40%). Since sildenafil (and its major circulating N-desmethyl metabolite) is 96% bound to plasma proteins, this results in the mean maximum free plasma concentration for sildenafil of 18 ng/mL (38 nM). Protein binding is independent of total drug concentrations.

In healthy volunteers receiving sildenafil (100 mg single dose), less than 0.0002% (average 186 mg) of the administered dose was present in ejaculate 90 minutes after dosing.

### Biotransformation

Sildenafil is cleared predominantly by the CYP3A4 (major route) and CYP2C9 (minor route) hepatic microsomal isoenzymes. The major circulating metabolite results from N-demethylation of sildenafil. This metabolite has a phosphodiesterase selectivity profile similar to sildenafil and an *in vitro* potency for PDE5 approximately 50% that of the parent drug. Plasma concentrations of this metabolite are approximately 40% of those seen for sildenafil. The N-desmethyl metabolite is further metabolised, with a terminal half-life of approximately 4 h.

### Elimination

The total body clearance of sildenafil is 41 L/h with a resultant terminal phase half-life of 3-5 h. After either oral or intravenous administration, sildenafil is excreted as metabolites predominantly in the faeces (approximately 80% of administered oral dose) and to a lesser extent in the urine (approximately 13% of administered oral dose).

## PRECLINICAL SAFETY DATA

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction and development.

## PHARMACEUTICAL PARTICULARS

### INCOMPATIBILITY

Not applicable.

### SHELF LIFE

24 months

### STORAGE CONDITION

Do not store above 30°C.

### NATURE AND CONTENTS OF CONTAINER

4 tablets packed in Alu- PVC/PVdC blister pack, 1 such blister is packed in a carton along with Patient Information Leaflet.

## MANUFACTURING AUTHORISATION HOLDER AND MANUFACTURER

Manufacturing Authorization Holder	Manufacturer
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Last Revision Date: Aug 03, 2023

# KAMAGRA CT

## Sildenafil Chewable Tablets (Orange Flavour)

### 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 CT is and what it is used for
2. What you need to know before you use Kamagra CT
3. How to use Kamagra CT
4. Possible side effects
5. How to store Kamagra CT
6. Contents of the pack and other information

### 1. What Kamagra CT is and what it is used for

Kamagra CT contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) 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.

Kamagra CT will only help you to get an erection if you are sexually stimulated.

Kamagra CT is a treatment for adult 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. What you need to know before you use Kamagra CT

#### Do not take Kamagra CT

- If you are allergic to sildenafil or any of the other ingredients of this medicine
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or "chest pain"). If you are not certain, 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 may also lead to a dangerous fall 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 secondary to blood clots). PDE5 inhibitors, such as

Kamagra CT 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 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 due to non-arteritic anterior ischaemic optic neuropathy (NAION).

### Warnings and precautions

- Talk to your doctor, pharmacist or nurse before taking Kamagra CT
- 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 deformity of your penis or Peyronie's Disease.
- If you have problems with your heart. 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 problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Kamagra CT and contact your doctor immediately.

You should not use Kamagra CT with any other oral or local treatments for erectile dysfunction.

You should not use Kamagra CT with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

You should not take Kamagra CT if you do not have erectile dysfunction.

You should not take Kamagra CT if you are a woman.

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 on a lower dose for you.

Special consideration for excipients and coloring agents

This tablet contains lactose and dextrose. You should tell your doctors if you have any rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose mal absorption disorders. If yes, then you should not take this medicine.

You should not take this medicines if you are allergic to Sunset yellow Lake FCF.

### Children and adolescents

Kamagra CT should not be given to individuals under the age of 18.

Other medicines and Kamagra CT

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

Kamagra CT tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken.

Kamagra CT and when you did. Do not take Kamagra CT with other medicines unless your doctor tells you that you can.

You should not take Kamagra CT if you are taking medicines called nitrates, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take Kamagra CT 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 fall in your blood pressure.

Tell your doctor or pharmacist if you are already taking riociguat.

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

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 Kamagra CT with alpha-blockers. This is most likely to happen within 4 hours after taking Kamagra CT. In order to reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start Kamagra CT. Your doctor may start you on a lower dose (25 mg) of Kamagra CT.

### 3. How to use Kamagra CT

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended starting dose is 50 mg.

You should not take Kamagra CT more than once a day.

You should take Kamagra CT about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

If you feel that the effect of Kamagra CT is too strong or too weak, talk to your doctor or pharmacist.

Kamagra CT will only help you to get an erection if you are sexually stimulated. The amount of time Kamagra CT takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Kamagra CT takes longer to work if you take it with a heavy meal.

If Kamagra CT 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 Kamagra CT than you should:

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

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

Contact your doctor if you take more tablets than you should.

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

### 4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. The side effects reported in association with the use of Kamagra CT are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Kamagra CT and seek medical help immediately:

- An allergic reaction -this occurs uncommonly (may affect up to 1 in 100 people). Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

- Chest pains -this occurs uncommonly

If this occurs during or after intercourse

- Get in a semi-sitting position and try to relax.

- Do not use nitrates to treat your chest pain.

- Prolonged and sometimes painful erections – this occurs rarely (may affect up to 1 in 1,000 people). If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

- A sudden decrease or loss of vision -this occurs rarely

- Serious skin reactions -this occurs rarely

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

- Seizures or fits -this occurs rarely

Other side effects:

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

Common (may affect up to 1 in 10 people): nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual disturbance, stuffy nose and dizziness.

*Uncommon (may affect up to 1 in 100 people):* vomiting, skin rash, eye irritation, bloodshot eyes/red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

*Rare (may affect up to 1 in 1,000 people):* fainting, stroke, heart attack, and irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely.

Of note most but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Kamagra CT.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. How to store Kamagra CT

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

Do not store above 30°C.

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.

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 protect the environment.

### 6. Contents of the pack and other information

#### What Kamagra CT contains:

The active ingredient is Sildenafil citrate 50 mg and 100 mg.

#### List of Excipients:

Sildenafil Citrate Mask Complex (Sildenafil Citrate and Instamask IC-MK-9014 White (which consist of Polyacrylic Resin, Carborane and Microcrystalline Cellulose)), Disintequik ODT (Lactose Monohydrate, Mannitol, Crospovidone and Dextrose Monohydrate), Colour Sunset Yellow Lake, Sucralose, Orange Flavour Powder 0473075 (Maltodextrin, Gum Arabic E 414, Silicon Dioxide E 551, Triacetin E 1518, Natural Flavouring Substance), Magnesium Stearate.

#### What Kamagra CT looks like and contents of the pack

Uncoated chewable tablet.

The tablets are packed in Alu- PVC/PVdC blister

4 Tablets packed in Alu- PVC/PVdC blister pack, 1 such blister is packed in a carton along with Package insert.

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For any information about this medicinal product, please contact Manufacturing Authorization Holder.

### DATE OF PUBLICATION OR REVISION

Aug 02, 2023