For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

3023595

Sildenafil Citrate Tablets IP
KAMAGRA* GOLD

How much **KAMAGRA GOLD** can I take?

Ans. The most convenient dose is decided by your doctor. **KAMAGRA GOLD** comes in different doses (50 mg & 100mg). For most men dose is 50mg. Do not take more **KAMAGRA GOLD** than your Doctor prescribes and do not take **KAMAGRA GOLD** more than once a day.

Who should not take **KAMAGRA GOLD** ?

Ans. **KAMAGRA GOLD** is only for men. It is not recommended for children and women. Patients who are on any cardiac medicine should consult the doctor regarding the use of **KAMAGRA GOLD**.

KAMAGRA GOLD should not be taken by patients who are on any form of nitrates.
Can I take **KAMAGRA GOLD** with alcohol?

Ans. You are advised not to take alcohol before taking **KAMAGRA GOLD**. It may alter the response of the drug.

Can I take **KAMAGRA GOLD** after food ?

Ans. Yes, but avoid fat meal before taking **KAMAGRA GOLD** to have better response.

What are the side effects of **KAMAGRA GOLD?**

Ans. **KAMAGRA GOLD** may cause side effects such as headache, flushing, stomach upset or blurring of vision.

What if **KAMAGRA GOLD** does not work?

KAMAGRA GOLD may not be effective for everyone, if it does not work for you, consult your doctor, for other treatment options.

Manufactured in India by :
ajanta pharma limited
Ajanta House, Charkop,
Kandivli (W), Mumbai - 400 067.

* Trade Mark

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Sildenafil Citrate Tablets IP
KAMAGRA* GOLD

KAMAGRA GOLD - 50 Tablet :

Each film coated tablet contains:
Sildenafil Citrate IP
Equivalent to Sildenafil 50 mg
Colours : Quinoline Yellow WS, Brilliant Blue FCF, & Titanium Dioxide IP

KAMAGRA GOLD – 100 Tablets:
Each film coated tablet contains:
Sildenafil Citrate IP
Equivalent to Sildenafil 100mg
Colours : Quinoline Yellow WS, Brilliant Blue FCF & Titanium Dioxide IP

DESCRIPTON

KAMAGRA GOLD (Sildenafil citrate) is the citrate salt of Sildenafil, a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specfic phosphodiesterase type 5(PDE5). Sildenafil citrate is designated chemically as 1-[{3-(6,7-dihydro-1-methy-7-oxo-3-propyl-1H-pyrozolo [4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate and has a molecular weight of 666.7.

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.

PHARMACOKINETICS

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.
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.
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.
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).

INDICATIONS
KAMAGRA GOLD is indicated for the treatment of erectile dysfunction.

CONTRA INDICATIONS
Consistent with its known effects on the nitric oxide/cGMP pathway, Sildenafil potentiates the hypotensive effects of nitrates, and its administration to patients who are using organic nitrates, either regularly and/or intermittently, in any form is therefore contraindicated. **KAMAGRA GOLD** is also contraindicated in patients with a known hypersensitivity to any component of the tablet.

PRECAUTIONS & WARNINGS
There is a potential for cardiac risk of sexual activity in patients with preexisting cardiovascular disease. Therefore, treatments for erectile dysfunction, including Sildenafil, should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status. Similarly, **KAMAGRA GOLD** should be prescribed with caution in the following group of patients since there is no controlled clinical trial data on the safety or efficacy of the drug in these patients:
Patients who have suffered a myocardial infarction, stroke, or life-threatening arrhythmia within the last 6 months;
Patients with resting hypotension (BP<90/50) or hypertension (BP>170-110);
Patients with cardiac failure or coronary artery disease causing unstable angina;
Patients with retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases).
Prolonged erection greater than 4 hours and priapism (painful erections greater than 6 hours in duration) have been reported infrequently with Sildenafil. In the event of an erection that persists longer than 4 hours, the patient should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result.
The safety of Sildenafil is unknown in patients with bleeding disorders and patients with active peptic ulceration. Sildenafil should be used with caution in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease) or in patients who have conditions which may predispose them to priapism (such as sickle cell anemia, multiple myeloma or leukemia).
The safety and efficacy of combinations of Sildenafil with other treatments for erectile dysfunction have not been studied. Therefore, the use of such combinations is not recommended.
Cases of visual defects have been reported spontaneously in connection with the intake of sildenafil and other PDE5 inhibitors. Patients should be advised that in the event of any sudden visual defect, they should stop taking **KAMAGRA GOLD** and consult a physician immediately.

Physicians should advise patients to stop taking PDE5 inhibitors, including sildenafil , and seek prompt medical attention in the event of sudden decrease or loss of hearing. These events, which may be accompanied by tinnitus and dizziness, have been reported in temporal association to the intake of PDE5 inhibitors, including sildenafil.

DRUG INTERACTIONS
A reduction in sildenafil clearance occurs when it was coadministered with CYP 3A4 inhibitors such as Ketoconazole, Erythromycin, or Cimetidine. Co-administration of ritonavir, a strong CYP3A4 inhibitor, greatly increased the systemic exposure of sildenafil (11-fold increase in AUC). A starting dose of 25 mg Sildenafil must be considered in such patients.
It can be expected that concomitant administration of CYP 3A4 inducers, such as Rifampicin, will decrease the plasma levels of Sildenafil.
Administration of sildenafil with nitric oxide donors such as organic nitrates or organic nitrites in any form is contraindicated.
When co-administering alpha-blockers with sildenafil, caution should be observed because of potential additive blood pressure-lowering effects. Co- administration with amlodipine may result in additional blood pressure reduction.

PREGNANCY, NURSING MOTHERS AND PAEDIATRIC USE

KAMAGRA GOLD is not indicated for use in newborns, children or women.

DOSAGE & ADMINISTRATION
For most patients, the recommended dose is 50 mg taken, as needed. Based on effectiveness and tolerance, the dose may be increased to a maximum recommended dose of 100 mg or decreased to 25 mg. The maximum recommended dosing frequency is once per day.
The following factors are associated with increased plasma level of Sildenafil : age>65 (40% increase in AUC), hepatic impairment (e.g. cirrhosis, 80%) severe renal impairment (creatininie clearance <30mL / min, 100%), and concomitant use of potent cytochrome P450 3A4 inhibitor [Ketoconazole, Itraconazole, Erythromycin (182%), Saquinavir (210%)]. Since higher plasma levels may increase both the efficacy and incidence of adverse events, a starting dose of 25 mg shoud be considered in these patients.

ADVERSE REACTIONS
Sildenafil is generally well tolerated. Commonly reported adverse events to Sildenafil include the following : headache (16%), dyspepsia (7%), nasal congestion (4%) and skin rash (2%). The most commonly reported adverse reactions in clinical studies among sildenafil treated patients were headache, flushing, dyspepsia, nasal congestion, dizziness, nausea, hot flush, visual disturbance and blurred vision.
Hypersensitivity, somnolence, hypoaesthesia, eye pain, photophobia, vertigo, tinnitus, tachycardia, palpitations, chest pain, vomiting, abdominal pain, dry mouth, rash, myalgia, fatigue, have rarely been reported with sildenafil.

OVERDOSAGE
In studies with healthy volunteers of single doses up to 800 mg, adverse events were similar to those seen at lower doses but incidence rates 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 is not eliminated in the urine.

PRESENTATION
Available in blister pack of 4 Tablets.

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

KEEP OUT OF THE REACH OF CHILDREN.

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