28-12-2022

94 x 140 mm

94mm

140mm

Sildenafil
Kadagra Rx

100 mg Film-Coated Tablet
Drugs used in Erectile Dysfunction

Formulation:
Each Film - Coated Tablet Contains :
Sildenafil (as citrate).....100mg

Indication :
For the management of erectile dysfunction.

Product Description:
Blue colored, diamond shaped, plain on both sides, biconvex film-coated tablet.

Pharmacokinetics:
Sildenafil is rapidly absorbed after a dose by mouth, with a bioavailability of about 40%. Peak plasma concentrations are attained within 30 to 120 minutes; the rate of absorption is reduced when sildenafil is given with food.
Sildenafil is widely distrubuted into tissues and is about 96% bound to plasma proteins. It is ,metabolised in the liver mainly by cytochrome P450 isoenzymes CYP3A4 (the major route) and CYP2C9. The major metabolite, –desmethyl sildenafil (UK-103320) also has some activity. The terminal half-lives of sildenafil and the N-desmethyl metabolite are about 4 hours.
Sildenafil is excreted as metabolites, mainly in the faeces, and to a lesser extent in the urine. Clearance may be reduced in the elderly and in patients with hepatic or severe renal impairment.

Dosage and Administration :
The usual dose is 50mg about 1 hour before sexual intercourse. The dose may be increased or decreased depending on response. The maximum recommended dose is 100mg and sildenafil should not be taken more often than once in 24 hours.

Precautions :
Caution is required in patients with hepatic or severe renal impairment, and dosage reduction of sildenafil may be necessary. Care is also needed in patients with anatomical deformation of the penis or haematological disorders that may predispose them to priapism. Patients who experience dizziness or visual disturbances should not drive or operate hazardous machinery.
The safety of sildenafil is uncertain in patients with severe hepatic impairment, bleeding disorders, active peptic ulceration, hypotension, a recent history of stroke, myocardial infarction, or life-threatening arrhythmia, unstable angina, heart failure, or retinal disorders such as retinitis pigmentosa (a minority of whom have genetic disorders of retinal phosphodiesterases). Licensed drug product information advises that it should not be used in these groups.
Cardiovascular disease.
For mention of a consensus statement on the use of sildenafil in patients with cardiovascular disease.

Contraindications :
Patients who use nitric oxide donors or nitrates in any form.
Men for whom sexual activity is inadvisable.
Women.

Adverse Effects :
Most commonly reported from sildenafil are headache, flushing and dyspesia. There may be visual disturbances, dizziness and nasal congestion. Other adverse effects reported include diarrhea, muscle pain, skin rashes and urinary or respiratory tract infection. Priapism has also occured. There have also been reports of serious cardiovascular events, including sudden cardiac death associated with the use of sildenafil. Effects on the Cardiovascular System: There have been considerable uncertainty about the potential cardiovascular risk associated with sildenafil treatment. Minor effects associated with vasodilation, eg headache and flushing are relatively common, but in patients without preexisting cardiovascular risk factors, the risk of cardiovascular events associated with the drug appears to be low.
Effects on the Eye: A bluish tinge or haze to vision and some increased light sensitivity has been reported by significant percentage of patients taking sildenafil, with percentage of reports increasing with increasing dose. Other visual disturbances reported in patients taking sildenafil have included temporary loss of vision and increased intraocular pressure.

Reporting of suspected adverse reactions:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary.
Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at first sign/s of adverse reactions.

Drug Interactions :
Sildenafil may potentiate the hypotensive effects of organic nitrates, and is therefore contraindicated in patients receiving such drugs. Concomitant administration of sildenafil with drugs that inhibit cytochrome P450 isoenzyme CYP3A4, eg cimetidine, erythromycin, itraconazole, ketoconazole and HIV-protease inhibitors may reduce sildenafil clearance necessitating a reduction in dosage. However, plasma concentrations of sildenafil are significantly increased by ritonavir, requiring even greater dosage reduction, and it is therefore strongly recommended that these 2 drugs are not given together.

Caution:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Availability :
Alu/clear PVC Blister pack x 4's (Box of 4's)

Storage :
Store at temperatures not exceeding 30°C.

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