Important Information. Please read carefully

VIVIC™

Xepa

VIVIC TABLET 100MG
Film-Coated Tablet

COMPOSITION
Each tablet contains 100mg Sildenafil (as Sildenafil Citrate).

PHARMACODYNAMICS
Sildenafil is an oral therapy for erectile dysfunction. It is a potent and selective inhibitor of the cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) in corpus cavernosum.
PDE5 is responsible for degradation of cGMP, which produces smooth muscle relaxation in the corpus cavernosum and allows inflow of blood to penis.
The physiological mechanism responsible for erection of the penis involves the release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. The NO is then activates enzyme guanylate cyclase, which results in increased levels of cGMP.
Sildenafil has a peripheral site of action on erections. It has no direct relaxant effect on isolated human corpus cavernosum but potently enhances the relaxant effect of NO.

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

INDICATIONS
Vivic is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

In order for sildenafil to be effective, sexual stimulation is required.

DOSAGE AND ADMINISTRATION
Adults - Usual oral dose is 50mg sildenafil about one hour before sexual intercourse. The dose may be adjusted according to response to 25-100mg. The maximum recommended dose is 100 mg sildenafil should not be taken more than once in 24 hours.
Onset of effect may be delayed if taken with food.
Elderly - Dosage adjustments are not required in elderly patients.
Patients with impaired hepatic function - Sildenafil clearance is reduced in patients with hepatic impairment. An initial oral dose of 25 mg is recommended.
Patients with impaired renal function - Sildenafil clearance is reduced in patients with severe renal impairment. An initial oral dose of 25 mg is recommended.
Patients using other medicines - An initial dose of no more than 25 mg daily is advised in patients taking sildenafil with inhibitors of cytochrome P450 isoenzyme CYP3A4 (refer Drug Interactions).
The dose should not exceed 25 mg every 48 hours if given with ritonavir-boosted HIV-protease inhibitors, although such a combination is best avoided entirely.
In patients stabilised on alpha blocker therapy, an initial dose of sildenafil 25 mg should be considered.

CONTRAINDICATIONS
Known hypersensitivity to sildenafil or any component of this product.
Contraindicated in patients receiving nitrates, in patients in whom vasodilation or sexual activity are inadvisable, in patients with a previous history of non-arteritic anterior ischaemic optic neuropathy (NAION), hypotension (systolic blood pressure below 90mmHg), recent stroke, unstable angina, and myocardial infarction.

WARNINGS AND 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. In the event of prolonged erection (for more than 4 hours), patients should seek medical assistance, as penile tissue damage and permanent loss of potency can occur.
Patients are also advised to stop taking sildenafil and seek medical advice in cases of sudden visual or hearing loss. Sildenafil should not be given to those with loss of vision in one eye caused by non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this was in connection with previous phosphodiesterase type-5 (PDE5) inhibitors or not.
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, hypertension, 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. Advise not be used in these groups.

DRUG INTERACTIONS
Sildenafil or other phosphodiesterase type-5 (PDE5) inhibitors may potentiate the hypotensive effects of organic nitrates, and are therefore contra-indicated in patients receiving such drugs.
Sildenafil may also enhance the hypotensive effect of nicorandil and use of the two drugs together should be avoided.
Symptomatic hypotension may also occur when PDE5 inhibitors are given with alpha blockers. Generally, the patient should be stabilised on alpha blocker therapy before the PDE5 is started at a low dose and adjusted according to response.
Drugs that inhibit the cytochrome P450 isoenzyme CYP3A4, such as cimetidine, delavirdine, erythromycin, itraconazole, and ketoconazole, may reduce the clearance of PDE5 inhibitors, necessitating a reduction in dosage.
Plasma concentrations of PDE5 inhibitors are significantly increased by HIV-protease inhibitors, and particularly so by ritonavir-boosted regimens. Such combinations should not be given unless absolutely essential.
Grapefruit juice should be avoided with sildenafil or other PDE5 inhibitors as it may increase their plasma concentrations. Inducers of CYP3A4, such as rifampicin, are likely to decrease plasma concentrations of PDE5 inhibitors. Bosentan also reduces exposure to sildenafil.

PREGNANCY AND LACTATION
Sildenafil is not indicated for use in women.

SIDE EFFECTS
Adverse effects most commonly reported with sildenafil are headache, flushing, and dyspepsia.
Also common are visual disturbances such as blurred vision, photophobia, chromatopsia, cyanopsia, eye irritation, pain and redness of the eyes. Retinal haemorrhage has occurred, and non-arteritic anterior ischaemic optic neuropathy (NAION) causing permanent loss of vision has been reported rarely.
Other common adverse effects include dizziness, insomnia, anxiety, vertigo, epistaxis, nasal congestion, pyrexia, and gastrointestinal disturbances such as diarrhoea and vomiting. Priapism can occur.
Other adverse effects include skin rashes, erythema, alopecia, limb and/or back pain, myalgia, facial oedema, fluid retention, paraesthesia, and urinary-tract infection. Dyspnoea, cough, rhinitis, sinusitis, bronchitis, and cellulitis can occur.
Sudden decrease or loss of hearing, anaemia, leucopenia, gynaecomastia, urinary frequency or incontinence, haematuria, and seizures have been reported.
Cerebrovascular haemorrhage and transient ischaemic attacks have occurred.
There have also been reports of palpitations, syncope, hypertension, hypotension, and serious cardiovascular events including myocardial infarction, arrhythmias, tachycardia, unstable angina, and sudden cardiac death.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE
Based on the reported studies of single doses up to 800mg, adverse events are similar to those seen at lower doses but incidence rates and severities are 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.

STORAGE CONDITION
Store below 30°C. Protect from moisture.

SHELF LIFE
The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION
Blue, oval shape, normal convex film-coated tablet engraved with 'V' marking on one side and plain on the reverse. Available as blister strips of 4's in packing of 4 tablets per box.

KEEP OUT OF REACH OF CHILDREN / JAUHI DARI KANAK-KANAK
For further information, please consult your pharmacist or physician.

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Manufactured and Marketed by
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