Evoke

(Sildenafil Tablets)

COMPOSITION:

Evoke 50mg Tablets

Each film coated tablet contains: 50mg Sildenafil (as citrate).

Evoke 100mg Tablets

Each film coated tablet contains: 100mg Sildenafil (as citrate).

PHARMACOLOGY:

Pharmacodynamics Properties:

Sildenafil is a potent and selective Phosphodiesterase type 5 (PDE5) inhibitor that restores impaired erection of the penis and helps maintain the same upon sexual stimulation. Erection of the penis occurs when Nitric Oxide (NO) is released from arginine by the action of Nitric Oxide Synthetase (NOS) following sexual stimulation. The elaboration NOS activates the enzyme Guanylate Synthetase which in turn increases the levels of cyclic Guanosine Monophosphate (cGMP). The cGMP produces relaxation of smooth muscles thus allowing inflow of blood into the corpus carvenosum to produce and maintain erection of the penis.

Degradation of cGMP by the enzyme PDE5 results in reduction of cGMP levels and therefore loss of erection. Sildenafil prevents this development by inhibiting PDE5.

Pharmacokinetic Properties :

Sildenafil is rapidly absorbed following oral administration and has a bioavability of approximately 40%. Peak Plasma concentrations are attained within 30 to 120 minutes, the rate of absorption being faster on an empty stomach.

Sildenafil is widely distributed in tissues and is about 96% bound to plasma proteins. It is metabolized in the liver mainly by cytochrome P450 isoenzymes, CYP3A4 being the major and CYP2C9 being the minor route. N-desmethylsildenafil is the major metabolite and has some activity.The terminal half-lives of Sildenafil and its major metabolite are about 4 hours.

About 80% of **Sildenafil** and its metabolites are excreted in the faeces and approximately 18% in urine. Clearance may be reduced in the elderly and in patients with hepatic or severe renal dysfunction.

INDICATIONS:

Sildenafil is for use in male adult of 18 years and above with erectile dysfunction of pyschogenic nature or organic causes such as prostatectomy, spinal cord injury and diabetes mellitus.

DOSAGE:

The recommended initial dose is 50mg taken 1 hour prior to sexual activity. Subsequent doses are adjusted to 25mg or 100mg in accordance with response as a single dose. Only one dose should be taken in a duration of 24 hours, the maximum dosage being 100mg.

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SIDE EFFECTS:

The most frequent side effects which may occur in about 1 in every ten patients is headache. Dizziness, visual disturbances, change in colour discrimination, flushing, nasal congestion and dyspepsia are the common side effects that may occur in about 1 to 10 patients in every 100 patients under treatment.

The frequent side effects that may occur in 1 to 10 out of every 1000 patients under treatment are; somnolence, vertigo, tinnitus, hypoaesthesia, palpitations, tachycardia, vomiting, nausea, dry mouth, skin rash, myalgia, chest pain, lacrimation, increased heart rate, conjunctival and other eye disorders.

The rare side effects are; hypersensitivity reactions, syncope, cerebrovascular accident, sudden decrease or loss of hearing, hypotension, hypertension, myocardial infarction, atrial fibrillation and epistaxis which may happen in 1 to 10 out of every 10,000 patients under treatment.

CAUTIONARY MEASURES :

Patients with severe renal impairment and hepatic impairment should be started at a lower dose of 25mg and adjusted upwards only if tolerated and in order to achieve the required efficacy. Patients on α-blocker therapy should be stabilized prior to initiating treatment with Evoke, starting with the lower dosage of 25mg and adjusting upwards only when tolerated and in order to obtain the required response.

Evoke should be used with caution in patients predisposed to priapism such as those with sickle cell anaemia, multiple myeloma and leukemia. It should also be used with caution in patients with anatomically deformed penis as in peyronies disease, angulation and carvenosal fibrosis.

Evoke may cause hypotension and dizziness, patients should be aware of their reaction to this drug before driving or operating a machinery.

CONTRAINDICATIONS:

Hypersensitivity to Sildenafil , severe hepatic impairment, patients with hypotension if systolic pressure is less than 90mm Hg, recent history of stroke, unstable angina, myocardial infarction and patients with known hereditary degenerative disorders of the retina such as retinitis pigmentosa and patients on ritonavir.

Evoke should not be used concomitantly with nitrates or nitric oxide donors such as amyl nitrite used in treatment of angina.

INTERACTIONS:

Itraconazole and other triazoles interact with Sildenafil increasing its concentration. Nitrates potentiate the hypotensive effects of Sildenafil.

OVERDOSAGE AND ITS COUNTERACTION:

The incidence of undesirable side effects increases with increased dose and without any significant increase in efficacy. Standard supportive overdosage treatment procedure should be carried out in case of overdosage where the adverse reactions become intolerable.

LEGAL CATEGORY: Prescription Only Medicine (POM).

SHELF LIFE : As per product label

STORAGE CONDITION: Store in a dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

DATE OF LAST REVIEW : June 2017

LICENCE HOLDER: LABORATORY & ALLIED LTD.

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