

Adegra[®]

Sildenafil

Description

Adegra[®] is a preparation of Sildenafil Citrate which is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5) and used as an oral therapy for erectile dysfunction. 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 has no direct relaxant effect on isolated human corpus cavernosum but enhances the effect of nitric oxide (NO) by inhibiting phosphodiesterase type 5 (PDE5) which is responsible for degradation of cGMP in the 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.

Indication

Adegra[®] is indicated for the treatment erectile dysfunction in men.

Dosage and Administration

Adult over 18 years: Initially 50 mg approximately 1 hour before sexual activity, subsequent doses adjusted according to response to 25–100 mg as a single dose as needed; maximum 1 dose in 24 hours. Maximum single dose is 100 mg.

The tablet should be swallowed whole with a glass of water. **Adegra[®]** should not be taken more than once a day. **Adegra[®]** can be taken with or without food but, onset of effect may be delayed if taken with food. The ability to get an erection may be temporarily impaired by drinking alcohol. To get the maximum benefit from the medicine, it is advised not to drink excessive amounts of alcohol before taking **Adegra[®]**.

Pediatric use

Adegra[®] should not be given to individuals under the age of 18.

Geriatric Use

Healthy elderly volunteers (65 years or over) had a reduced clearance of sildenafil. Since higher plasma levels may increase both the efficacy and incidence of adverse events, a starting dose of 25 mg should be considered.

Use in Pregnancy and Lactation

Adegra[®] is not indicated for use by women.

Special considerations for patients with kidney or liver problems

Patients with kidney or liver problems should start with a lower dose (25mg).

Side effects

The side-effects of Sildenafil include dyspepsia, nausea, vomiting, headache (including migraine), flushing, dizziness, myalgia, back pain, visual disturbances (non-arteritic anterior ischaemic optic neuropathy has been reported. Drug should be stopped if sudden visual impairment occurs) and nasal congestion. Less common side-effects include painful red eyes, palpitation, tachycardia, hypo/hypertension and epistaxis. Other side-effects reported rarely include syncope, hypersensitivity reactions (including rash, facial oedema, and Stevens-Johnson syndrome) and priapism. Serious cardiovascular events (including arrhythmia, unstable angina, and myocardial infarction), seizures, sudden hearing loss and retinal vascular occlusion have also been reported.

Contraindications

Sildenafil is contra-indicated in patients receiving nitrates, in patients in whom vasodilation or sexual activity are inadvisable or in patients with a previous history of non-arteritic anterior ischaemic optic neuropathy. In the absence of information, manufacturers contra-indicate these drugs in hypotension (should be avoided if systolic blood pressure below is 90 mmHg), recent stroke, unstable angina, and myocardial infarction. Sildenafil Citrate is contraindicated in patients with known hypersensitivity to any component of the tablet.

Drug interactions

Sildenafil metabolism is principally mediated by the cytochrome P450 (CYP) isoforms 3A4 (major route) and 2C9 (minor route). Therefore, inhibitors of these isoenzymes may reduce Sildenafil clearance and inducers of these isoenzymes may increase Sildenafil clearance.

Precautions

Sildenafil should be used with caution in cardiovascular disease (e.g. left ventricular outflow obstruction), anatomical deformation of the penis (e.g. angulation, cavernosal fibrosis, Peyronie's disease) and in those with a predisposition to priapism (e.g. in sickle-cell disease, multiple myeloma or leukaemia). Concomitant treatment with a phosphodiesterase type-5 inhibitor and an alpha-blocker can increase the risk of postural hypotension. Patient should be stable on alpha-blocker therapy prior to initiating a phosphodiesterase type-5 inhibitor (at a low dose).

Driving and using machinery

Sildenafil can cause dizziness and affect vision. Cautions should be taken before driving or using machinery.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light. Keep away from the reach of children.

Presentation

- Adegra**[®] 25 mg tablet : Each coated tablet contains Sildenafil 25 mg as Citrate INN
- Adegra**[®] 50 mg tablet : Each coated tablet contains Sildenafil 50 mg as Citrate INN
- Adegra**[®] 100 mg tablet : Each coated tablet contains Sildenafil 100 mg as Citrate INN

Package quantities

- Adegra**[®] 25 mg tablet : Carton of 4 tablets in blister strips.
- Adegra**[®] 50 mg tablet : Carton of 4 tablets in blister strips.
- Adegra**[®] 100 mg tablet : Carton of 4 tablets in blister strips.

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