

Ciaton[®]

Tadalafil

Description

Ciaton[®] is a preparation of Tadalafil, which is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). Penile erection during sexual stimulation is caused by increased penile blood flow resulting from the relaxation of penile arteries and corpus cavernosal smooth muscle. This response is mediated by the release of Nitric oxide (NO) from nerve terminals and endothelial cells, which stimulates the synthesis of cGMP in smooth muscle cells. cGMP causes smooth muscle relaxation and increased blood flow into the corpus cavernosum. The inhibition of phosphodiesterase type 5 (PDE5) by Tadalafil enhances erectile function by increasing the amount of cGMP. The inhibition of PDE5 by Tadalafil has no effect in the absence of sexual stimulation because sexual stimulation is required to initiate the local release of nitric oxide.

Indication

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

Dosage and Administration

Adults over 18 years: The recommended starting dose of Ciaton[®] in most patients is 10mg at least 30 minutes before sexual activity, subsequent doses adjusted according to response, up to 20mg as a single dose; maximum one dose can be taken in 24 hours. For patients who anticipate sexual activity at least twice weekly, 5mg once daily can be taken and the dose can be reduced to 2.5mg once daily according to response. Ciaton[®] can be taken without regard to food.

Elderly: Dosage adjustments are not required in elderly patients. Dosage recommendations described for adults can be applied to elderly men.

Renal Impairment: No dose adjustment is required in patients with mild renal insufficiency. For patients with moderate renal insufficiency (creatinine clearance 31 to 50 mL/min), a starting dose of 5mg not more than once daily is recommended and the maximum dose should be limited to 10mg not more than once in every 48 hours. For patients with severe renal insufficiency (creatinine clearance <30 mL/min) on hemodialysis, the maximum recommended dose is 5mg.

Hepatic Impairment: There are no available data for doses higher than 10mg of Tadalafil in patients with hepatic impairment.

Diabetes: Dosage adjustments are not required in diabetics.

Use in pregnancy & lactation: Tadalafil is not indicated for use by women.

Use in children: Tadalafil should not be used in individuals <18 years of age.

Side effects

The most commonly reported adverse events are headache and dyspepsia occurring in approximately 11% and 7% of patients respectively. The adverse events reported with Tadalafil were generally mild or moderate, transient and decreased with continued dosing. Other common adverse events are back pain, myalgia, nasal congestion and flushing. Swelling of eyelids, sensations described as eye pain, conjunctival hyperaemia and dizziness are uncommon adverse events.

Contraindication

Administration of Tadalafil to patients who are using any form of organic nitrate, either regularly and/or intermittently is contraindicated. In clinical pharmacology studies, Tadalafil was shown to potentiate the hypotensive effect of nitrates. Tadalafil is contraindicated for patients with a known hypersensitivity to Tadalafil or any component of the tablet.

Drug Interaction:

Effects of other medicinal products on Tadalafil

Although specific interactions have not been studied, some protease inhibitors, such as ritonavir and saquinavir and other CYP3A4 inhibitors, such as erythromycin, clarithromycin, itraconazole and grapefruit juice, should be co administered with caution as they would be expected to increase plasma concentrations of Tadalafil. Concomitant administration of other CYP3A4 inducers, such as rifampicin, phenobarbital, phenytoin and carbamazepine will also decrease plasma concentrations of Tadalafil.

Effects of Tadalafil on other medicinal products

In clinical studies, Tadalafil (10 mg) was shown to augment the hypotensive effects of nitrates. Therefore, administration of Tadalafil to patients who are using any form of organic nitrate is contra-indicated.

Tadalafil (10 mg) had no clinically significant effect on the plasma concentration of warfarin, nor did Tadalafil affect changes in prothrombin time induced by warfarin. Tadalafil (10 mg) did not potentiate the increase in bleeding time caused by acetylsalicylic acid. In clinical pharmacology studies, the potential for Tadalafil to augment the hypotensive effects of antihypertensive agents was examined. Concomitant administration of Tadalafil with the major classes of antihypertensive agents were studied, including calcium channel blockers (amlodipine), angiotensin converting enzyme (ACE) inhibitors (enalapril), beta-adrenergic receptor blockers (metoprolol), thiazide diuretics (bendrofluazide) and angiotensin II receptor blockers did not affect the hypotensive effect of these drugs. Tadalafil (10 mg, except for studies with angiotensin II receptor blockers and amlodipine in which a 20 mg dose was applied) had no clinically significant interaction with any of these classes. No

changes in Tadalafil concentrations were seen 3 hours after co-administration with alcohol. When Tadalafil 10 mg was administered with theophylline in a clinical pharmacology study, there was no pharmacokinetic interaction. The only pharmacodynamic effect was a small increase in heart rate. Specific interaction studies with antidiabetic agents were not conducted.

Precautions

Evaluation of erectile dysfunction should include an appropriate medical assessment to identify potential underlying causes, as well as treatment options. Before prescribing Tadalafil, it is important to note the following: Cardiovascular status of patients, interaction with other medicines like Nitrates, alpha-blockers, antihypertensive, potent inhibitors of cytochrome P4503A4 (CYP3A4), substantial consumption of alcohol, sudden loss of vision, sudden loss of hearing, renal insufficiency and hepatic impairment.

There have been rare reports of prolonged erections greater than 4 hours and priapism (painful erections greater than 6 hours in duration) for this class of compounds. Priapism, if not treated promptly, can result in irreversible damage to the erectile tissue. Patients who have an erection lasting greater than 4 hours, whether painful or not, should seek emergency medical attention.

Pharmaceutical precautions

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

Presentation

- Ciaton® 5 mg tablet : Each coated tablet contains Tadalafil INN 5mg
- Ciaton® 10 mg tablet : Each coated tablet contains Tadalafil INN 10mg
- Ciaton® 20 mg tablet : Each coated tablet contains Tadalafil INN 20mg

Package quantities

- Ciaton® 5 mg tablet : Carton of 4 tablets in blister pack.
- Ciaton® 10 mg tablet : Carton of 4 tablets in blister pack.
- Ciaton® 20 mg tablet : Carton of 4 tablets in blister pack.

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