Rocktec® (Tadalafil 20mg) Film Coated Tablets safety card

- **Dosage and administration:**

Adults
Tadalafil is indicated for the treatment of Treatment of erectile dysfunction in adult males.
In order for Tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.
Tadalafil is indicated for the treatment of moderate to severe manic episode.
In patients whose manic episode has responded to Tadalafil treatment, Tadalafil is indicated for the prevention of recurrence in patients with bipolar disorder.

- **Precautions**:

Before treatment with ROCKTEC
A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes, before pharmacological treatment is considered.
Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients, since there is a degree of cardiac risk associated with sexual activity. Tadalafil has vasodilator properties, resulting in mild and transient decreases in blood pressure and as such potentiates the hypotensive effect of nitrates .
The evaluation of erectile dysfunction should include a determination of potential underlying causes and the identification of appropriate treatment following an appropriate medical assessment. It is not known if ROCKTEC is effective in patients who have undergone pelvic surgery or radical non-nerve-sparing prostatectomy.

Cardiovascular
Serious cardiovascular events, including myocardial infarction, sudden cardiac death, unstable angina pectoris, ventricular arrhythmia, stroke, transient ischaemic attacks, chest pain, palpitations and tachycardia, have been reported either post marketing and/or in clinical trials. Most of the patients in whom these events have been reported had pre-existing cardiovascular risk factors. However, it is not possible to definitively determine whether these events are related directly to these risk factors, to ROCKTEC, to sexual activity, or to a combination of these or other factors.
In patients who are taking alpha1 blockers, concomitant administration of ROCKTEC may lead to symptomatic hypotension in some patients. The combination of tadalafil and doxazosin is not recommended.
Vision
Visual defects and cases of NAION have been reported in connection with the intake of ROCKTEC and other PDE5 inhibitors. Analyses of observational data suggest an increased risk of acute NAION in men with erectile dysfunction following exposure to tadalafil or other PDE5 inhibitors. As this may be relevant for all patients exposed to tadalafil, the patient should be advised that in case of sudden visual defect, he should stop taking ROCKTEC and consult a physician immediately .

Decreased or sudden hearing loss
Cases of sudden hearing loss have been reported after the use of tadalafil. Although other risk factors were present in some cases (such as age, diabetes, hypertension and previous hearing loss history) patients should be advised to stop taking tadalafil and seek prompt medical attention in the event of sudden decrease or loss of hearing.
Hepatic impairment (tadalafil 10 mg and 20 mg)
There is limited clinical data on the safety of single-dose administration of ROCKTEC in patients with severe hepatic insufficiency (Child-Pugh Class C). If ROCKTEC is prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician.
Priapism and anatomical deformation of the penis
Patients who experience erections lasting 4 hours or more should be instructed to seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.
ROCKTEC, should be used with caution in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis, or Peyronie's disease) or in patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia).
Use with CYP3A4 inhibitors
Caution should be exercised when prescribing ROCKTEC to patients using potent CYP3A4 inhibitors (ritonavir, saquinavir, ketoconazole, itraconazole, and erythromycin), as increased tadalafil exposure (AUC) has been observed if the medicinal products are combined .
ROCKTEC and other treatments for erectile dysfunction

The safety and efficacy of combinations of ROCKTEC and other PDE5 inhibitors or other treatments for erectile dysfunction have not been studied. The patients should be informed not to take ROCKTEC in such combinations.

Lactose

ROCKTEC contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

- **Contraindications:**

Hypersensitivity to the active substance or to any of the excipients.
administration of ROCKTEC to patients who are using any form of organic nitrate is contraindicated.
ROCKTEC must not be used in men with cardiac disease for whom sexual activity is inadvisable.
The following groups of patients with cardiovascular disease were not included in clinical trials and the use of tadalafil is therefore contraindicated:
- patients with myocardial infarction within the last 90 days,
- patients with unstable angina or angina occurring during sexual intercourse,
- patients with New York Heart Association Class 2 or greater heart failure in the last 6 months,
- patients with uncontrolled arrhythmias, hypotension (<90/50 mm Hg), or uncontrolled hypertension,
- patients with a stroke within the last 6 months.

ROCKTEC is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection or not with previous PDE5 inhibitor exposure.
The co-administration of PDE5 inhibitors, including tadalafil, with guanylate cyclase stimulators, such as riociguat, is contraindicated as it may potentially lead to symptomatic hypotension

- **Pregnancy and lactation:**

Pregnancy

There are limited data from the use of tadalafil in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of ROCKTEC during pregnancy.

Breastfeeding

Available pharmacodynamic/toxicological data in animals have shown excretion of tadalafil in milk. A risk to the suckling child cannot be excluded. ROCKTEC should not be used during breast feeding.

(This card focuses on major safety information for medicinal products in order to minimize possible side effects that arise from improper use of medicinal products).

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