

## RAVANA® Tablets

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

### **Information about RAVANA**

RAVANA tablets for oral use is available in two doses 20 mg and 5 mg containing respectively 20 mg and 5 mg of tadalafil with the following ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

RAVANA tablets are for use by men only.

Tadalafil is a selective inhibitor of cyclic guanosine monophosphate (c-GMP)-specific phosphodiesterase type 5 (PDE5). Tadalafil causes smooth muscle relaxation and increases blood flow into the corpus cavernosum. Tadalafil is used orally as vasoactive therapy to facilitate attainment of a sexually functional erection in males with erectile dysfunction.

RAVANA is indicated in the following conditions:

- Treatment of erectile dysfunction of various severities (ED)
- Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)
- Treatment of erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (ED/BPH)

RAVANA significantly improves ability to achieve an erection sufficient for vaginal penetration and to maintain the erection long enough for successful intercourse.

RAVANA is effective only in case of adequate sexual stimulation presence.

### **The way to take RAVANA**

RAVANA can be taken without regards to meals.

*RAVANA 20mg for use as needed for erectile dysfunction:*

Patients usually achieve an erection sufficient for successful intercourse within 30 minutes after administration. However, because of the prolonged duration of action (up to 36 hours) of tadalafil, timing of administration relative to anticipated sexual activity is less important than with relatively short-acting drugs for erectile dysfunction.

The usual initial oral dose of tadalafil in men is 10 mg taken before anticipated sexual activity.

Depending on effectiveness and tolerance, the dose subsequently may be increased to a maximum of 20 mg or decreased to 5 mg. The maximum recommended dosing frequency in most patients is once daily.

*RAVANA 5 mg for once daily use for erectile dysfunction:*

The recommended daily dose is 2.5 mg taken once daily without regard to timing of sexual activity and may be increased to 5 mg upon efficacy and tolerability.

*RAVANA 5 mg for once daily use for benign prostatic hyperplasia*

The recommended daily dose is 5 mg taken at the same time every day.

*RAVANA 5 mg for once daily use for erectile dysfunction and benign prostatic hyperplasia:*

The recommended daily dose is 5 mg taken at the same time every day, without regard to timing of sexual activity.

### **In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

### **In case of missed dose**

If you miss a dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

### **Contraindications**

This drug is contraindicated in case of:

- Hypersensitivity to tadalafil or any other components
- Concomitant use of nitrates or nitrites either regularly and/or intermittently

**Precautions**

- A medical history and physical examination should be undertaken to diagnose erectile dysfunction and determine potential underlying causes, before pharmacological treatment is considered.

Your doctor will consider your cardiovascular status prior to initiating any treatment for erectile dysfunction, since there is a degree of cardiac risk associated with sexual activity.

- Inform your doctor before using this medication in case of the presence of cardiovascular or cerebrovascular disease, peptic ulcer disease, liver or kidney disease, history of severe vision loss or eye disease.

- Discontinue the treatment and seek immediate medical attention if sudden decrease or loss of hearing or of vision occurs or if anginal pain occurs after using this drug.

- The use of this drug is not recommended in patients with a recent myocardial infarction or stroke; those with uncontrolled arrhythmias, hypotension or uncontrolled hypertension; those with heart failure; or those with unstable angina or angina occurring during sexual intercourse and in patients with severe hepatic failure.

- Drugs indicated for the treatment of erectile dysfunction must be used with caution in patients with anatomical deformation of the penis or in patients who have conditions that might predispose them to priapism (such as sickle cell anemia, multiple myeloma, or leukemia).

- Seek immediate medical attention if an erection persists longer than 4 hours or is painful.

-This drug is not recommended in combination with alpha-blockers for the treatment of BPH because the efficacy of this combination has not been adequately studied and due to the risk of blood pressure lowering.

-This drug is not indicated for use in women and in individuals younger than 18 years of age.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant use of organic nitrates or nitrites either regularly and/or intermittently is contraindicated.

Concomitant use with alpha blockers or antihypertensive agent can potentiate their hypotensive effect.

Do not use alcohol excessively when taking this drug.

Drugs such as itraconazole, ketoconazole, erythromycin, HIV protease inhibitors and grapefruit juice can increase tadalafil exposure.

Drugs such as rifampin, phenobarbital, phenytoin and carbamazepine can decrease tadalafil exposure.

**Adverse reactions**

Most common adverse reactions include headache, dizziness, dyspepsia, abdominal pain, back pain, myalgia, nasal congestion, flushing.

Visual disturbances and priapism have been reported rarely.

Please inform your doctor if any side effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

RAVANA, tadalafil 20 mg, pack of 2 tablets

RAVANA, tadalafil 5 mg, pack of 30 tablets

**Issue date:** 10/2011

RAVT2/002