



PACKAGE LEAFLET

HARDCIS 5 mg Film Coated Tablets

Taken by mouth

Active substance: Each film coated tablet contains 5 mg tadalafil.

Excipients: Lactose monohydrate (from cow's milk), microcrystalline cellulose, hydroxypropyl cellulose-L, sodium lauryl sulfate, croscarmellose sodium, magnesium stearate,

Opadry II yellow 32K520009: lactose monohydrate (from bovine milk), HPMC 2910/Hypromellose 15cP, yellow iron oxide, titanium dioxide, triacetin, talc

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

In this leaflet:

- 1. What HARDCIS is and what it is used for***
- 2. What you need to know before you take HARDCIS***
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1. WHAT HARDCIS IS AND WHAT IT IS USED FOR

HARDCIS 5 mg is a yellow, almond-shaped, film coated tablet. It is available in blister packs of 14 or 28 tablets.

HARDCIS belongs to the group of medicines called phosphodiesterase type 5 inhibitors.

HARDCIS 5 mg is used in the treatment of the following diseases in adult men:

Erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity. Following sexual stimulation HARDCIS works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. HARDCIS will not help you if you do not have erectile dysfunction.

It is important to note that HARDCIS for the treatment of erectile dysfunction does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Lower urinary tract symptoms associated with benign prostatic enlargement (benign prostatic hyperplasia), which is a condition that can be defined as the prostate glands gets bigger with age, difficulty in starting to urinate, incomplete emptying of the bladder, and the need to urinate more



frequently, even at night. HARDCIS improves blood flow to, and relaxes the muscles of, the prostate and bladder, which may reduce symptoms of benign prostatic hyperplasia. Tadalafil has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HARDCIS

Do not take HARDCIS

- If you are allergic (hypersensitive) to tadalafil, or any other ingredients of HARDCIS.
- If you are medications containing nitric oxide in any form, such as organic nitrate or amyl nitrite. This group of medicines (nitrates) is used in the treatment of chest pain due to coronary heart disease (angina pectoris). Tadalafil has been shown to increase the effects of these drugs. Inform your doctor if you are using any form of nitrate or if you are unsure.
- If you have serious heart disease or recently had a heart attack within the last 90 days.
- If you have unstable chest pain or chest pain during sexual intercourse.
- If you have had a “Class 2” or more severe heart failure in the last 6 months according to the New York Heart Association classification.
- If you have an uncontrolled heart rhythm disorder (arrhythmia).
- If you have very low blood pressure (<90/50 mm Hg) or you have uncontrolled high blood pressure.
- If you have had a recent (within the last 6 months) stroke.
- If you ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), also known as stroke of the eye.
- If you are taking riociguat. This medicine is used to treat high blood pressure in the lung (pulmonary arterial hypertension) and high blood pressure in the lung due to a blood clot (chronic thromboembolic pulmonary hypertension). PDE5 inhibitors such as HARDCIS have been shown to increase the blood pressure lowering effect of this drug. Talk to your doctor if you are taking riociguat or if you are unsure.

Take special care with HARDCIS

Talk to your doctor before taking HARDCIS.

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem, you should tell your doctor.

Since benign prostate enlargement (benign prostatic hyperplasia) and prostate cancer may have similar symptoms, your doctor should check you for prostate cancer or other similar urological signs before starting treatment for benign prostatic hyperplasia. The use of HARDCIS in the treatment of prostate cancer is not recommended.

The following reasons are the reasons why HARDCIS may not be suitable for you. If any of these apply to you, talk to your doctor before taking this medicine:

- An abnormality of red blood cells (sickle cell anemia), cancer of the bone marrow (multiple myeloma), cancer of the blood cells (leukemia), or a deformity of the penis.
- A serious liver problem.
- A severe kidney disorder
- Frequent and prolonged erection of the penis without any sexual desire.



It is not known whether HARDCIS is effective in patients who have undergone a surgery involving the formations in the lower back and pelvis (pelvic surgery), or radical prostatectomy, which is defined as the removal of the prostate gland together with some tissues around it, where the nerve is not preserved.

If you experience sudden decrease or loss of vision, stop taking HARDCIS and contact your doctor immediately.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking HARDCIS and contact your doctor immediately.

HARDCIS is not intended for use by women.

Taking HARDCIS with food and drink:

You can take HARDCIS on an empty or full stomach.

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well HARDCIS will work and should be taken with caution. Talk to your doctor for further information.

Pregnancy

Not applicable.

Breastfeeding

Not applicable.

Fertility (Childbearing potential)

When dogs were treated, there was a decrease in sperm development in the testicles. A reduction in sperm count was seen in some men. These effects are unlikely to lead to a lack of fertility

Driving and using machines

Dizziness has been reported in some men taking tadalafil in clinical trials. Therefore, you should check how you react to tablets before driving or using machines.

Important information about some of the ingredients of HARDCIS

HARDCIS contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Concomitant use with other medicines

It is very important to inform your doctor or pharmacist, especially if you are being treated with nitrates, because you should not use HARDCIS with nitrates.

If you are going to use the following drugs together with HARDCIS, inform your doctor or pharmacist as HARDCIS or the mentioned drugs may be affected:

- Medicines called non-selective alpha-blockers (sometimes used to treat high blood pressure or urinary tract symptoms accompanying benign prostate enlargement).
- Other medicines to treat high blood pressure.



- Riociguat.
- A 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- Medicines such as ketoconazole (for the treatment of fungal infections) and protease inhibitors for the treatment of AIDS or HIV infection.
- Phenobarbital, phenytoin and carbamazepine (medicines used against convulsions).
- Rifampicin, erythromycin, clarithromycin or itraconazole (medicines used to treat bacterial and fungal infections)
- Other treatments for erectile dysfunction.

If your doctor has told you that you cannot use it, do not use HARDCIS with other medicines.

If you are undergoing erectile dysfunction treatment, do not use HARDCIS with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

3. HOW TO TAKE HARDCIS

Instructions for proper use and dose/frequency of administration:

When using HARDCIS, always take it exactly as your doctor has told you. If you are unsure, consult your doctor or pharmacist.

The recommended dose is one 5 mg tablet once a day, taken at approximately the same time each day. Your doctor may adjust the dose according to your response to HARDCIS. HARDCIS tablets are for oral administration.

Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take HARDCIS, avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

For the treatment of erectile dysfunction

Usually, the recommended dose is 10 mg (2x5 mg) taken at least 30 minutes before the anticipated sexual activity. The dose may be increased to 20 mg in patients where 10 mg (2x5 mg) tadalafil does not show an adequate effect.

A maximum of 1 daily dose should be used.

Tadalafil doses of 10 mg (2x5 mg) or 20 mg should be taken before the anticipated sexual activity and is not recommended for continuous daily use.

In patients who require more frequent use of tadalafil (e.g. at least twice a week) before intercourse, the lowest daily dose may be considered according to the patient's preference and the physician's evaluation.

The recommended dose in these patients is 5 mg once a day, but the dose can be reduced to 2.5 mg once a day according to individual tolerability. The suitability of the daily regimen for continuous use should be re-evaluated periodically.



When taken once a day HARDCIS allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of HARDCIS may be useful to men who anticipate having sexual activity 2 or more times per week. It is important to note that HARDCIS does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Drinking alcohol may affect your ability to get an erection.

In the treatment of lower urinary tract symptoms due to benign prostate enlargement (benign prostatic hyperplasia) and in the treatment of patients with both erectile dysfunction and benign prostatic hyperplasia:

The recommended dose is one 5 mg tablet once a day, taken at approximately the same time each day. Alternative treatment options should be considered in patients who cannot tolerate the use of 5 mg tadalafil or when this dose is not effective.

For products containing 5 mg of tadalafil (except for scored tablets) the product is not suitable for splitting.

DO NOT TAKE HARDCIS more than once a day.

Route and method of administration:

HARDCIS tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

Different age groups

Use in children:

HARDCIS is not suitable for use by children and adolescents under the age of 18.

Special use cases:

It has no special use.

If you feel that the effect of HARDCIS is too strong or too weak, talk to your doctor or pharmacist.

If you take more HARDCIS than you should

If you have taken more HARDCIS than you should, talk to a doctor or pharmacist.

You may experience side effects described in section 4.

If you forget to take HARDCIS

Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, consult your doctor or pharmacist. You should not take HARDCIS more than once a day.

Effects that may occur when treatment with HARDCIS is stopped

No effects are to be expected after discontinuation of treatment.



4. POSSIBLE SIDE EFFECTS

Like all medicines, there may be side effects in people who are sensitive to the substances contained in HARDCIS. These effects are normally mild to moderate in nature.

All of the side effects in this leaflet are listed as shown in the following categories:

- Very common : may occur in at least 1 in 10 patients
Common : may occur in less than 1 in 10 patients, but 1 or more in 100 patients.
Uncommon : may occur in less than 1 in 100 patients, but 1 or more in 1,000 patients.
Rare : may occur in less than 1 in 1,000 patients, but 1 or more in 10,000 patients.
Very rare : may occur in less than 1 in 10,000 patients.
Unknown : cannot be estimated from the available data.

If any of the following occur, stop using HARDCIS and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Allergic reactions (including rashes (frequency: uncommon)).
- Chest pain - do not use nitrates but seek immediate medical assistance (frequency: uncommon).
- Priapism, a prolonged and possibly painful erection after taking HARDCIS (frequency: rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- Sudden loss of vision (frequency: rare).

Other reported side effects:

Common

- Headache
- Back pain
- Muscle aches
- Pain in arms and legs
- Facial flushing
- Nasal congestion
- Indigestion

Uncommon

- Dizziness
- Stomach ache
- Nausea
- Vomiting
- Reflux
- Blurred vision
- Eye pain
- Difficulty in breathing
- Presence of blood in urine
- Prolonged erection
- Pounding heartbeat sensation
- A fast heart rate
- High blood pressure
- Low blood pressure
- Nose bleeds and ringing in the ears



- Swelling of the hands, feet or ankles
- Feeling tired

Rare

- Fainting
- Seizures and transient memory loss
- Swelling of the eyelids
- Red eyes
- Sudden decrease or loss of hearing
- Hives (itchy red welts on the surface of the skin)
- Blood coming from the urinary tract
- Presence of blood in semen
- Increased sweating

Heart attack and stroke have been reported in men taking tadalafil. Most of these men had known heart problems before taking this medicine.

Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional rare side effects reported in men taking tadalafil in clinical trials:

Migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.

Dizziness side effects have been reported more frequently in men over 75 years of age taking tadalafil. Diarrhea side effects have been reported more frequently in men over 65 years of age using tadalafil.

If you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HARDCIS

Keep HARDCIS out of the sight and reach of children and in its package.

Store at room temperature below 25°C.

Use this medicine in line with the expiry date.

Do not use HARDCIS after the expiry date which is stated on packaging.

Do not use HARDCIS if you notice any defect on product and/or its package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.



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Module 1.3.1 Package Leaflet



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