**PROPOSED CLEAN PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:**

S4

**CIAVOR 5 – 5 mg Film coated tablets**

Tadalafil

Contains Lactose

Read all of this leaflet carefully before you start taking CIAVOR 5

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- CIAVOR 5 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**


1. What CIAVOR 5 is and what it is used for
2. What you need to know before you take CIAVOR 5
3. How to take CIAVOR 5
4. Possible side effects
5. How to store CIAVOR 5
6. Contents of the pack and other information

## 1. What CIAVOR 5 is and what it is used for

CIAVOR 5 is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. CIAVOR 5 has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

CIAVOR 5 contains the active substance tadalafil which belongs to a group of medicines called Phosphodiesterase type 5 inhibitors. Following sexual stimulation CIAVOR 5 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. CIAVOR 5 will not help you if you do not have erectile dysfunction.

It is important to note that CIAVOR 5 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.

## 2. What you need to know before you take CIAVOR 5

Do not take CIAVOR 5 if you:

- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).
- are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines (“nitrates”) used in the treatment of angina pectoris (“chest pain”). CIAVOR 5 has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.
- have serious heart disease or recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- have a severe hepatic (liver) insufficiency (Child-Pugh Class C).

- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- if you have had previously experienced of a decrease or loss of hearing in one or both ears, with or without dizziness.

**Warnings and precautions**

Talk to your doctor before taking CIAVOR 5.

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.

Before taking the tablets, tell your doctor if you have:

- sickle cell anaemia (an abnormality of red blood cells).
- multiple myeloma (cancer of the bone marrow).
- leukaemia (cancer of the blood cells).
- any deformation of your penis.
- a serious liver problem.
- a severe kidney problem.

It is not known if CIAVOR 5 is effective in patients who have had:

- pelvic surgery.
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical nonnerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking CIAVOR 5 and contact your doctor immediately.

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 CIAVOR 5 and contact your doctor immediately.

CIAVOR 5 is not intended for use by women.

**Children and adolescents**

CIAVOR 5 is not intended for use by children and adolescents under the age of 18.

**Other medicines and CIAVOR 5**

Tell your doctor if you are taking, have recently taken or might take any other medicines. Do not take CIAVOR 5 if you are already taking nitrates.

Some medicines may be affected by CIAVOR 5 or they may affect how well CIAVOR 5 will work. Tell your doctor or pharmacist if you are already taking:

- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- a 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

**CIAVOR 5 with drink and alcohol**

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well CIAVOR 5 will work and should be taken with caution. Talk to your doctor for further information.

**Driving and using machines**

Some men taking CIAVOR 5 in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

**CIAVOR 5 contains lactose**

If you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take CIAVOR 5

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

CIAVOR 5 tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

**The recommended dose** is one 5 mg tablet taken once a day at approximately the same time of the day.

Do not take CIAVOR 5 more than once a day.

Once a day dosing of CIAVOR 5 may be useful to men who anticipate having sexual activity two or more times per week.

When taken once a day CIAVOR 5 allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day.

It is important to note that CIAVOR 5 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 and may temporarily lower your blood pressure. If you have taken or are planning to take CIAVOR 5, avoid excessive drinking (blood alcohol level of 0,08 % or greater), since this may increase the risk of dizziness when standing up.

**If you take more CIAVOR 5 than you should**

Contact your doctor. You may experience side effects described in section 4.

**If you forget to take CIAVOR 5**

Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet. You should not take CIAVOR 5 more than once a day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate in nature.

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).
- priapsim, a prolonged and possibly painful erection after taking CIAVOR 5 (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 side effects have been reported*:

Common (seen in 1 to 10 in every 100 patients)

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and indigestion.

*Uncommon (seen in 1 to 10 in every 1 000 patients)*

- dizziness, stomach ache, feeling sick, being sick (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, ringing in the ears, swelling of the hands, feet or ankles and feeling tired.

*Rare (seen in 1 to 10 in every 10 000 patients)*

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.
- Heart attack and stroke have also been reported rarely in men taking CIAVOR 5. 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 have been reported in men taking CIAVOR 5 that were not seen in clinical trials. These include:

- 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.

The side effect dizziness has been reported more frequently in men over 75 years of age taking CIAVOR 5. Diarrhoea has been reported more frequently in men over 65 years of age taking CIAVOR 5.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CIAVOR 5.

## 5. How to store CIAVOR 5

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after ‘EXP’. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Do not store above 25 °C. 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.

## 6. Contents of the pack and other information What CIAVOR 5 contains

- The active substance is tadalafil. Each tablet contains 5 mg of tadalafil.

- The other ingredients are:

**Tablet core**: lactose monohydrate (see end of section 2), croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurilsulfate, magnesium stearate.

Film-coat: lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), iron oxide yellow (E172), talc.

**What CIAVOR 5 looks like and contents of the pack**

CIAVOR 5 is a light-yellow film-coated tablet in the shape of an almond and has "C 5" marked on one side.

CIAVOR 5 is available in blister packs containing 14 or 28 tablets. Not all pack sizes may be marketed.

**Holder of the Certificate of Registration**

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