

PATIENT INFORMATION LEAFLET

CIAVOR 20

Read all of this leaflet carefully before you start using CIAVOR 20.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CIAVOR 20 has been prescribed for you personally and you should not share your CIAVOR 20 with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S4

NAME OF THE MEDICINAL PRODUCT

CIAVOR 20 (tablets)

WHAT CIAVOR 20 CONTAINS

The active substance is tadalafil. Each film-coated tablet contains 20 mg of tadalafil.

The other ingredients are:

Tablet core: lactose monohydrate, croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurylsulfate, magnesium stearate.

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

WHAT CIAVOR 20 IS USED FOR

CIAVOR 20 is a treatment for men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

CIAVOR 20 belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation CIAVOR 20 acts 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 20 will not help you if you do not have erectile dysfunction.

It is important to note that CIAVOR 20 does not work if there is no sexual stimulation.

BEFORE YOU TAKE CIAVOR 20

Do not take CIAVOR 20:

- if you 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 20 has been shown to increase the effects of these medicines. If you are taking any form of nitrate or if you are unsure tell your doctor.
- if you have serious heart disease or have had a recent heart attack.
- if you have had a recent stroke.
- if you have low blood pressure or uncontrolled high blood pressure.
- if you are allergic (hypersensitive) to tadalafil or any of the other ingredients of CIAVOR 20.
- if you have a severe kidney problem.
- if you have had previous experience of a decrease or loss of hearing in one or both ears, with or without dizziness
- if you have ever had an experience of partial, sudden, temporary or permanent decrease or loss of vision in one or both eyes.

Take special care with CIAVOR 20

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.

In case of chest pain occurring during or after sexual activity you should NOT use nitrates but you should seek immediate medical assistance.

The following are reasons why CIAVOR 20 may also not be suitable for you.

If any of them apply to you, talk to your doctor before you take CIAVOR 20:

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

CIAVOR 20 is not intended for use by women or by children under the age of 18.

Taking CIAVOR 20 with food and drink

You may take CIAVOR 20 with or without food.

Driving and using machines

As dizziness has been reported in men taking CIAVOR 20 in clinical studies, you should be aware of how you react to CIAVOR 20 before you drive or use machinery.

Information for men intolerant of lactose, one of the ingredients of CIAVOR 20:

CIAVOR 20 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CIAVOR 20.

Taking other medicines with CIAVOR 20

Always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed, because they might interact with CIAVOR 20. This is particularly important if you are treated with nitrates as you should not take CIAVOR 20 if you are taking these medicines.

A type of medicine called an alpha blocker is sometimes used to treat high blood pressure or an enlarged prostate. Tell your doctor if you are being treated for either of these conditions. Do not take CIAVOR 20 with other medicines if your doctor tells you that you may not.

You should not use CIAVOR 20 together with any other treatments for erectile dysfunction.

HOW TO TAKE CIAVOR 20

Always take CIAVOR 20 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended maximum dose is 20 mg CIAVOR 20 before sexual activity. CIAVOR 20 tablets are for oral use. Swallow the tablet whole with some water. You may take CIAVOR 20 with or without food.

You may take a CIAVOR 20 tablet at least 30 minutes before sexual activity. CIAVOR 20 may still be effective up to 36 hours after taking the tablet. It is important to note that CIAVOR 20 does not work if there is no sexual stimulation.

Drinking alcohol may affect your ability to get an erection. Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take CIAVOR 20, avoid excessive drinking (blood alcohol level of 0.08 % or greater), since this may increase the risk of dizziness when standing up.

You should NOT take CIAVOR 20 more than once a day. CIAVOR 20 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

If you take more CIAVOR 20 than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest poison control centre.

If you forget to take CIAVOR 20

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of CIAVOR 20, ask your doctor or pharmacist.

SIDE EFFECTS

CIAVOR 20 can cause side effects.

Not all side effects reported for this medicine are included in the leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Frequently reported side effects in patients taking CIAVOR 20 include headache, indigestion, back pain, muscle aches, facial flushing, dizziness and nasal congestion.

Less frequently reported side effects are allergic reactions including rashes, abdominal pain, heartburn, blurred vision, eye pain, increased sweating, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure and chest pain.

In case of chest pain occurring during or after sexual activity you should NOT use nitrates but you should seek immediate medical assistance.

Other less frequent side effects in patients taking CIAVOR 20 include fainting, seizures (fits) and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives and nose bleeds.

It is possible that a prolonged and possibly painful erection may occur after taking CIAVOR 20.

If you have such an erection, which lasts continuously for more than 4 hours, you should contact a doctor immediately.

Heart attack and stroke have also been reported in men taking CIAVOR 20. Most, but not all of these men, had known heart problems before taking CIAVOR 20.

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

Additional side effects reported in men taking CIAVOR 20 include migraine, swelling of the face, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, chest pain, and sudden heart death.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORAGE AND DISPOSAL INFORMATION

Store at or below 25 °C. Keep the blisters in the outer carton until required for use.

Keep out of reach of children.

Do not use CIAVOR 20 after the expiry date stated on the carton and blister.

CIAVOR 20 should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of CIAVOR 20 no longer required. These measures will help to protect the environment.

PRESENTATION

CIAVOR 20 (Tablets), TA 4464, are available as aluminium/PVC or aluminium PVC/PE/PCTFE blister strips packed in cartons of 2, 4 or 8 tablets.

IDENTIFICATION

The tablets are yellow film-coated and almond shaped, marked 'F49' on one side.

REGISTRATION NUMBERS

36/7.1.5/0385

NAME & BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION

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15 August 2013