

Patient Information Leaflet

SCHEDULING STATUS

S4

CIATAD 5 mg tablet

CIATAD 20 mg tablet

Tadalafil

Contains lactose:

Each 5 mg film coated tablet contains 81, 70 mg lactose (as monohydrate).

Each 20 mg film coated tablet contains 326,80 mg lactose (as monohydrate)

Read all of this leaflet carefully before you start taking CIATAD

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

1. What CIATAD is and what it is used for

CIATAD contains the active substance tadalafil. CIATAD 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.

Tadalafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Following sexual stimulation tadalafil works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is an improved erection. Tadalafil will not help you if you do not have erectile dysfunction. It is important to note that tadalafil 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 any medicines for erectile dysfunction.

2. What you need to know before you take CIATAD

Do not take CIATAD:

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of CIATAD (listed in section 6.1)
- if you are taking any form of a group of medicines called nitrates. These are used in the treatment of angina.
- if you have serious heart disease or recently had a heart attack within the last 90 days
- if you recently had a stroke within the last 6 months.
- If you have low blood pressure or uncontrolled high blood pressure.
- If you have a severe hepatic (liver) insufficiency (Child-Pugh Class C)
- If you have ever had loss of vision because of a condition called non-arteritic anterior ischemic optic neuropathy (NAION), also described as “stroke of the eye”. This may or may not have been connected to taking a medicine like tadalafil.
- If you have previously experienced loss of hearing in one or both ears, with or without symptoms like vertigo and dizziness.

Warnings and precautions

Tell your doctor if you have a history of heart disease. Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart.

Take special care with CIATAD:

- If you are taking medicines to control your blood pressure as the dosage of these medicines might have to be adjusted to prevent your blood pressure from dropping too low.
- if you notice any symptoms or feel any discomfort when you begin sexual activity, stop immediately and report the incident to your doctor.
- And let your doctor know immediately If you experience sudden loss of vision or any change in vision
- And let your doctor know immediately if you experience a sudden loss of hearing or decrease in ability to hear. You may experience dizziness and ringing in your ears with this loss of hearing.
- If you have kidney or liver disease
- If you experience prolonged erections (4 hours or more) while taking tadalafil. If this is not treated immediately it can lead to permanent damage and loss of potency.
- If you have any malformations of the penis
- If you suffer from a type of anaemia called sickle cell anaemia or any type of cancer.
- If you are taking other medication for erectile dysfunction as CIATAD should not be taken with certain other medicines (see section “Other medicines and CIATAD” below).

It is not known if CIATAD 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 non nerve-sparing prostatectomy).

CIATAD is not intended for use by women.

Children and adolescents

CIATAD is not intended for use by children and adolescents under the age of 18

Other medicines and CIATAD

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Please talk to your doctor or pharmacist if you are taking any of the following medicines:
 - Medicines to control your blood pressure
 - Ketoconazole, itraconazole (used to treat fungal infections)
 - Rifampicin (used to treat tuberculosis)
 - Medicines used for the treatment and control of seizures (fits)
 - Ritonavir, saquinavir (used in the treatment of HIV/AIDS)
 - Antacids (used to neutralise acid in the stomach)

CIATAD with food and drink

- CIATAD may be taken with or without food.
- Grapefruit juice may affect how well CIATAD will work and should be taken with caution.
- 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 CIATAD, avoid excessive drinking (blood alcohol level of 0,08 % or greater), since this may increase the risk of dizziness when standing up.

Pregnancy, breastfeeding and fertility

- CIATAD is not indicated for use in women. If you and your partner are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.
- You should not use this medicine during pregnancy.
- You should not breast-feed while using CIATAD.

Driving and using machines

- You may experience dizziness while using CIATAD.
- It is not always possible to predict to what extent CIATAD may interfere with the daily activities of a

patient.

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CIATAD affects them.

CIATAD contains lactose

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

CIATAD contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take CIATAD

- Do not share medicines prescribed for you with any other person.
- Always take CIATAD exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is 5 mg once daily at approximately the same time of the day.
- The maximum dose is 20 mg a day.
- You should not take CIATAD more than once in a day.
- CIATAD 20 mg may be taken up to 36 hours or as early as 16 minutes prior to when you want to engage in sexual activity.
- Swallow the tablet whole with a glass of water.
- If you have the impression that the effect of CIATAD is too strong or too weak, tell your doctor or pharmacist.

If you take more CIATAD than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre. You may experience headache, discomfort in your stomach, back or muscle pain

and an erection that lasts longer than 4 hours.

If you forget to take CIATAD

If you forget to take CIATAD, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CIATAD can have side effects.

Not all side effects reported for CIATAD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIATAD, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking CIATAD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty breathing
- Severe skin rash or itching
- Swollen tongue or lips

These are all very serious side effects. If you have them, you may have had a serious reaction to CIATAD. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain
- An erection that lasts longer than 4 hours
- Sudden loss of vision

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Headache
- Reddening of the face (flushing)
- Stuffy nose
- Discomfort in your stomach
- Back pain, pain in your muscles or any part of your body

Less frequent side effects

- Dizziness
- Loss of consciousness or numbness on one side of the body
- Fainting, severe headache (migraine), sudden memory loss
- Blurred vision or loss of vision, eye pain, swelling of eyelids, redness or itching of the eye
- Ringing in ears, loss of hearing
- Changes in heart rhythm, chest pain or feeling of pressure in chest
- Low or high blood pressure
- Difficulty breathing, nose bleeds
- Stomach pain, nausea, vomiting, heartburn or burning sensation in your throat
- Rash, sweating
- Blood in urine
- Prolonged erections, blood in the sperm or bleeding from the penis
- Chest pain, tiredness, swelling of the legs or face

Frequency unknown side effects

- An emergency when part of the eye (the retina) pulls away from the supportive tissue that

provides necessary oxygen and nourishment

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting 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 CIATAD.

5. How to store CIATAD

Store all medicines out of reach of children.

- Store at or below 25 °C
- Store in the original package / container
- Protect from light / moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- There are no special storage instructions for CIATAD

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information

What CIATAD contains

The active substance is tadalafil.

Each **CIATAD** tablet contains 5 mg or 20 mg of tadalafil

The other ingredients are:

Tablet core:

Colloidal silicone dioxide, croscarmellose sodium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, povidone (K-25), sodium lauryl sulphate

Film-coat:

Opadry Yellow 03F52005

Composition of coating material:

Hypromellose (E464), iron oxide yellow (E172), macrogol (E1521), talc (E553b), titanium dioxide (E171)

What CIATAD looks like and contents of the pack

5 mg:

Yellow to light yellow, round shaped, bevelled edge, coated tablets debossed with '337' on one side and plain on other side.

20 mg:

Yellow to light yellow, oval shaped, beveled edge, coated tablets debossed with 'L339' on one side and plain on other side.

Ciatad 5 tablets are available in blister packs. The blisters are packed into cartons and each carton contains 30 tablet

Ciatad 20 tablets are available in blister packs. The blisters are packed into cartons and each carton contains 2 or 4 tablets

HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

a SUN PHARMA company

Roodepoort, 1724

South Africa

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