

PATIENT INFORMATION LEAFLET FOR CAVERFIL

SCHEDULING STATUS: S4

CAVERFIL 5, 5 mg film-coated tablet

CAVERFIL 20, 20 mg film-coated tablet

Tadalafil

Contains sugar: Lactose monohydrate

CAVERFIL 5: Each film-coated tablet contains 149,40 mg of lactose monohydrate.

CAVERFIL 20: Each film-coated tablet contains 288,80 mg of lactose monohydrate.

Contains sodium:

CAVERFIL 5: Each film-coated tablet contains 11,5 mg croscarmellose sodium and 0,60 mg sodium lauryl sulphate.

CAVERFIL 20: Each film-coated tablet contains 23,0 mg croscarmellose sodium and 1,20 mg sodium lauryl sulphate.

Read all of this leaflet carefully before you start taking CAVERFIL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.

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

1. What CAVERFIL is and what it is used for

CAVERFIL contains the active substance tadalafil.

CAVERFIL 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 CAVERFIL

Do not take CAVERFIL

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of CAVERFIL (listed in **section 6**).
- 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.
- 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).
- 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 CAVERFIL:

- 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 have experienced the following:
 - a heart attack in the last 90 days
 - angina (a chest pain which feels like pressure or squeezing in your chest) during sexual intercourse
 - heart failure in the last 6 months
 - uncontrolled low or high blood pressure or a problem with the rhythm of your heartbeat
 - a stroke in the last 6 months
- 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 CAVERFIL should not be taken with certain other medicines (see section “**Other medicines and CAVERFIL**” below).

It is not known if CAVERFIL 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).

Children and adolescents

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

Other medicines and CAVERFIL

- Always tell your health care 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).

CAVERFIL with food and drink

- CAVERFIL may be taken with or without food.
- Grapefruit juice may affect how well CAVERFIL 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 CAVERFIL, 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

- CAVERFIL 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 health care provider for advice before taking this medicine.
- You should not use this medicine during pregnancy.
- You should not breast-feed while using CAVERFIL.

Driving and using machines

- You may experience dizziness while using CAVERFIL.

It is not always possible to predict to what extent CAVERFIL 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 CAVERFIL affects them.

CAVERFIL contains lactose monohydrate

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

CAVERFIL contains sodium

CAVERFIL 5 contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

CAVERFIL 20 contains 24,2 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0,012 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take CAVERFIL

- Do not share medicines prescribed for you with any other person.
- Always take CAVERFIL 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 CAVERFIL more than once in a day.
- CAVERFIL 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.
- Your doctor will tell you how long your treatment with CAVERFIL will last.
- If you have the impression that the effect of CAVERFIL is too strong or too weak, tell your doctor or pharmacist.

If you take more CAVERFIL 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 CAVERFIL

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

4. Possible side effects

CAVERFIL can have side effects.

Not all side effects reported for CAVERFIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CAVERFIL, please consult your health care provider for advice.

If any of the following happens, stop taking CAVERFIL 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 CAVERFIL. You may need urgent medical attention or hospitalisation.

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.

Side effects with unknown frequency:

- Retinal detachment

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of CAVERFIL.

5. How to store CAVERFIL

Store at or below 25 ° C.

Store all medicines out of reach of children.

Store in the original carton.

Do not use after the expiry date printed on the blister or carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What CAVERFIL contains

The active substance is tadalafil.

CAVERFIL 5: Each film-coated tablet contains 5 mg tadalafil.

CAVERFIL 20: Each film-coated tablet contains 20 mg tadalafil.

The other ingredients are lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, sodium lauryl sulphate, magnesium stearate, Opadry yellow (hypromellose, iron oxide red, iron oxide yellow, talc, titanium dioxide, triacetin) and Opadry II yellow (hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, triacetin).

What CAVERFIL looks like and contents of the pack

Film-coated tablet.

CAVERFIL 5: Pale pinkish yellow, circular, biconvex, film-coated tablet with “T5” debossed on one side and plain on other side.

CAVERFIL 20: Yellow coloured, capsule shaped, biconvex, film-coated tablet with “T20” debossing on one side and plain on other side.

CAVERFIL 5 is packed in:

- A plain aluminium blister foil and PVC/PE/PVDC film clear transparent of 28 (2 x 14s) and 30 (3 x 10s) film-coated tablets.
- 50 cc HDPE Bottle, with Argus LOC Blue CR Cap containing 30 and 90 film-coated tablets.

CAVERFIL 20 is packed in:

- A plain aluminium blister foil and PVC/PE/PVDC film clear transparent of 2, 4 or 8 film-coated tablets.
- 50 cc HDPE Bottle, with Argus LOC Blue CR Cap containing 30 film-coated tablets.
- 60 cc HDPE Bottle, with Argus LOC Blue CR Cap containing 90 film-coated tablets.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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CAVERFIL 20: 51/7.1.5/0035.033

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE
HOLDER:
The QR Code
to be
generated and
included after
approval.