**APPROVED LEAFLET**

**SCHEDULING STATUS**

S4

**CYFIL 2,5 (Film coated tablets)**

**CYFIL 5 (Film coated tablets)**

**CYFIL 20 (Film coated tablets)**

Tadalafil

Contains lactose:

Each 2.5 mg film coated tablet contains 45,786 mg lactose (as monohydrate).

Each 5 mg film coated tablet contains 91,572 mg lactose (as monohydrate).

Each 20 mg film coated tablet contains 367,584 mg lactose (as monohydrate).

**Read all of this leaflet carefully before you start taking Cyfil**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Cyfil 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 Cyfil is and what it is used for
2. What you need to know before you take Cyfil
3. How to take Cyfil
4. Possible side effects

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5. How to store Cyfil

6. Contents of the pack and other information

## 1. What Cyfil is and what it is used for

- Cyfil contains the active substance tadalafil.
- 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 Cyfil

**Do not take Cyfil:**

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of Cyfil (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 severe liver disease.
- 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**

Before being treated with Cyfil, your doctor will conduct a full medical history and physical examination to find out if there are any underlying causes for your condition.

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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 Cyfil:

- 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 Cyfil should not be taken with certain other medicines (see section “Other medicines and Cyfil” below)

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**Other medicines and Cyfil**

- 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)

**Cyfil with food and drink**

- Cyfil may be taken with or without food.

**Pregnancy, breastfeeding and fertility**

- Cyfil 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 Cyfil.

**Driving and using machines**

- You may experience dizziness while using Cyfil.
- It is not always possible to predict to what extent Cyfil 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 Cyfil affects them.

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**Cyfil 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.

## 3. How to take Cyfil

- Do not share medicines prescribed for you with any other person.
- Always take Cyfil exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is 2,5 mg to 5 mg daily.
- The maximum dose is 20 mg a day.
- You should not take Cyfil more than once in a day.
- Cyfil 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 Cyfil is too strong or too weak, tell your doctor or pharmacist.

**If you take more Cyfil 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 Cyfil**

If you forget to take Cyfil, take it as soon as you remember. Do not take a double dose to make up for forgotten doses. You should not take Cyfil more than once in a day.

## 4. Possible side effects

- Cyfil can have side effects.
- Not all side effects reported for Cyfil are included in this leaflet. Should your general health worsen or if you

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experience any untoward effects while taking Cyfil, please consult your doctor, pharmacist or other healthcare professional for advice.

- If any of the following happens, stop taking Cyfil 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 Cyfil. 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:
    - <u>Frequent side effects</u>
        - Headache
        - Reddening of the face (flushing)
        - Stuffy nose
        - Discomfort in your stomach
        - Back pain, pain in your muscles or any part of your body
    - <u>Less frequent side effects</u>
        - Dizziness

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- 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, loosening of the retina
- 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

- 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 Cyfil.

## 5. How to store Cyfil

- Store all medicines out of reach of children.
- Store at or below 25 °C.

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## 6. Contents of the pack and other information

**What Cyfil contains**

- The active substance is tadalafil.
- Each film coated tablet contains 2,5 mg, 5 mg or 20 mg tadalafil.
- The other ingredients are:
    - *Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, s*orbitan stearate, *magnesium stearate*
    - *Film coating (Opadry II 32K580004 white, Opadry II 32K520007 yellow & Opadry II 32K520009 yellow):* Hypromellose, lactose monohydrate, titanium dioxide, iron oxide yellow (Opadry II 32K520007 yellow & Opadry II 32K520009 yellow), triacetin, talc

**What Cyfil looks like and contents of the pack**

- Cyfil 2,5 (film coated tablets) are white to off-white, round, biconvex, bevelled edged, film coated tablets, debossed with “T” on one side and “25” on other side.
- Cyfil 5 (film coated tablets) are light yellow, capsule shaped, biconvex, bevelled edged, film coated tablets, debossed with “T 5” on one side and plain on the other side.
- Cyfil 20 (film coated tablets) are yellow, capsule shaped, biconvex, bevelled edged, film coated tablets, debossed with “T 20” on one side and plain on the other side.
- Cyfil 2,5; 5 & 20 are packed in PVC/PE/PVdC-Aluminium blister pack, comprising PVC/PE/PVdC laminated, nontoxic rigid film as forming foil and hard tempered aluminium foil with HSL coating on bright side as lidding foil.

Pack sizes:

Cyfil 2.5: 28 tablets

Cyfil 5: 14, 28, 30, 84 or 90 tablets

Cyfil 20: 2, 4, 8, 12, 56 or 60 tablets

- Not all pack sizes will be marketed.

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**HOLDER OF CERTIFICATE OF REGISTRATION**

**Accord Healthcare (Pty) Ltd**

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