

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

SENTALIS 5 mg Tadalafil

SENTALIS 20 mg Tadalafil

Contains lactose:

Each 5 mg film coated tablet contains 50 mg lactose (as monohydrate).

Each 20 mg film coated tablet contains 200 mg lactose (as monohydrate).

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

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

1. What **SENTALIS** is and what it is used for

SENTALIS contains the active substance tadalafil.

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SENTALIS is a treatment for men with erectile dysfunction. This 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 **SENTALIS**

Do not take **SENTALIS:**

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of **SENTALIS** (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.
- 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.

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Take special care with **SENTALIS**:

- 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 anemia called sickle cell anemia or any type of cancer.
- If you are taking other medication for erectile dysfunction as **SENTALIS** should not be taken with certain other medicines (see section "Other medicines and **SENTALIS**" below).

It is not known if **SENTALIS** 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

SENTALIS is not intended for use by children and adolescents under age 18.

Other medicines and SENTALIS

- 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: *VR*

- Medicines to control your bloodpressure
- Ketoconazole, itraconazole (used to treat fungalinfections)
- Rifampicin (used to treattuberculosis)
- Medicines used for the treatment and control of seizures(fits)
- Ritonavir, saquinavir (used in the treatment ofHIV/AIDS)
- Antacids (used to neutralise acid in the stomach)

SENTALIS with food and drink

- **SENTALIS** may be taken with or withoutfood.
- Grapefruit juice may affect how well **SENTALIS** 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 **SENTALIS**, 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

- **SENTALIS**is not indicated for use in women. If you and your partner are planning to have a baby, pleaseconsult your doctor, pharmacist or other healthcare provider for advice before taking thismedicine.
- You should not use this medicine duringpregnancy.
- You should not breast-feed while using**SENTALIS**.

Driving and using machines

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

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SENTALIS contains lactose

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

SENTALIS contains sodium

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

3. How to take SENTALIS

- Do not share medicines prescribed for you with any other person.
- Always take **SENTALIS** 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 daily at approximately the same time of day.
- The maximum dose is 20 mg a day.
- You should not take **SENTALIS** more than once in a day.
- **SENTALIS 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 **SENTALIS** is too strong or too weak, tell your doctor or pharmacist.

If you take more SENTALIS 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 SENTALIS

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

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4. Possible sideeffects

- **SENTALIS** can have sideeffects.
- Not all side effects reported for **SENTALIS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SENTALIS**, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, stop taking **SENTALIS** 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 **SENTALIS**. 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 sideeffects
 - Headache
 - Reddening of the face (flushing)
 - Stuffy nose
 - Discomfort in your stomach
 - Back pain, pain in your muscles or any part of your body

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- Less frequent sideeffects
 - 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, nosebleeds
 - 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

- retinal detachment (which may appear as tiny specks through your field of vision).

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

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information on the safety of **SENTALIS**.

5. How to store SENTALIS

Store at or below 25 °C (room temperature).

Keep the blisters in the carton until required for use.

Keep the HDPE container tightly closed.

Store in the original package in order to protect from light and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister / label/ carton/ bottle.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What SENTALIS contains

Each film coated tablet contains 5 mg or 20 mg tadalafil.

Other ingredients include:

Tablet core contains:

Croscarmellose sodium, microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide, povidone, sodium lauryl sulphate, sodium citrate dihydrate, sodium stearyl fumarate.

Film coating contains:

Hypromellose (E464), triacetin (E1518), talc (E553b), titanium dioxide (E171), and iron oxide yellow (E172).

What SENTALIS looks like and contents of the pack

SENTALIS 5 mg:

Yellow coloured, almond shaped, biconvex film coated tablets having 'L 62' debossed on one side and plain on other side.

SENTALIS 20 mg:

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Yellow coloured, almond shaped, biconvex film coated tablets having 'L 64' debossed on one side and plain on other side.

Contents of the pack:

HDPE Container Pack:

Tablets are packed in round, white HDPE container with child resistant closure with pulp and heat seal liner.

Pack size include 30's tablets.

Blister Pack:

Tablets are packed in clear PVC / PVdC foil as the forming material and plain aluminium foil with heat seal lacquer as the lidding material.

Pack size include:

SENTALIS 5 mg – Pack size include 10's, 14's, 28's or 100's tablets.

SENTALIS 20 mg - Pack size include 2's, 4's, 8's, 10's or 100's tablets.

Not all pack sizes are necessarily marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd
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1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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