

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

MAKLITIO 20 mg (film-coated)

Sildenafil Citrate equivalent to 20 mg sildenafil active base

Sugar free.

Read all of this leaflet carefully before you start taking MAKLITIO

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

1. What MAKLITIO is and what it is used for

MAKLITIO contains the active ingredient sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE5). **MAKLITIO** is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs). **MAKLITIO** brings down blood pressure by widening these vessels.

2. What you need to know before you take **MAKLITIO**

Do not take **MAKLITIO**:

- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of **MAKLITIO** listed in Section 6.
- If you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of angina pectoris (or “chest pain”). **MAKLITIO** can cause a serious increase in the effects of these medicines. Tell your doctor if you are taking any of these medicines. If you are not certain, ask your doctor or pharmacist.
- If you are taking erythromycin (used to treat certain infections), ketoconazole or itraconazole to treat fungal infections you should not take **MAKLITIO**.
- If you are taking ritonavir or saquinavir therapy for the treatment of HIV, you should not take **MAKLITIO**.
- If you have a severe liver problem where your liver is not functioning normally.
- If you have severe renal problem, where your kidney is not functioning normally.
- If your blood pressure is below 90/50 mmHg.

If you are not sure whether you should take **MAKLITIO**, contact your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking **MAKLITIO**

Tell your doctor if you have:

- If you have a severe heart problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure at rest.
- If you have high blood pressure.
- If you have certain rare inherited eye disease (such as retinitis pigmentosa).
- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow), or any disease or deformity of the penis.

- If you currently have a stomach ulcer, a bleeding disorder (such as haemophilia) or problems with nose bleeds.
- If your disease is due to a blocked or narrow vein rather than a blocked or narrow artery.
- If your liver does not work properly.
- If you take medicines for erectile dysfunction.

Special considerations for patients with kidney or liver problems:

You should tell your doctor if you have kidney or liver problems.

If you are not sure whether you should take **MAKLITIO**, contact your doctor.

MAKLITIO should not be given to children under the age of 18.

Other medicines and MAKLITIO

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is especially important to inform your doctor if you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MAKLITIO** with these medicines may cause undesirable interactions.

- If you are taking bosentan therapy for pulmonary hypertension ask your doctor or pharmacist for advice before taking **MAKLITIO**, as your dose may need to be adjusted.
- Tell your doctor if you are already taking riociguat.
- **MAKLITIO** may cause a serious increase in the effects of medicines called nitrates and nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often used for the relief of angina pectoris (or “chest pain”). You should not take **MAKLITIO** if you are taking these medicines.
- If you are taking erythromycin, clarithromycin, telithromycin (these are antibiotics used to treat certain bacterial infections), ketoconazole or itraconazole to treat fungal infections you should not take **MAKLITIO**.
- If you are taking ritonavir or saquinavir therapy for the treatment of HIV, you should not take **MAKLITIO**.

- If you are taking alpha-blocker therapy for the treatment of high blood pressure or prostate problems, ask your doctor or pharmacist for advice before taking **MAKLITIO**.

MAKLITIO TABLETS with food and drink:

You should not drink grapefruit juice when you are taking **MAKLITIO**.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking sildenafil.

Pregnancy:

You should not take **MAKLITIO** if you are pregnant.

Breastfeeding:

Stop breastfeeding when you start **MAKLITIO** treatment. It is not known if the medicine passes into the breast milk.

Driving and using machines

MAKLITIO can cause dizziness and effects on vision. You should not drive or operate machinery until you know how treatment with **MAKLITIO** affects you.

3. How to take MAKLITIO

Do not share medicines prescribed for you with any other person.

Always take **MAKLITIO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Take **MAKLITIO** by mouth. **MAKLITIO** can be taken with or without food. Swallow the tablet whole with a glass of water.

The usual dose is:

The recommended dose is 20 mg (one tablet) three times a day (taken 6 to 8 hours apart) swallowed with or without food.

Your doctor will tell you how long your treatment with **MAKLITIO** will last.

If you have the impression that the effect of **MAKLITIO** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MAKLITIO than you should

You will likely have a headache, diarrhoea, pains in your back or hands and legs.

You should not take more tablets than your doctor tells you to.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and the rest of the remaining **MAKLITIO** with you so the doctor will know what you have taken.

If you forget to take MAKLITIO TABLET:

If you forget to take **MAKLITIO**, take a dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take your tablets at the usual times. Do not take a double dose to make up for forgotten tablets.

4. Possible side effects

MAKLITIO can have side effects.

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

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

- Swelling of face, tongue or throat
- Difficulties in swallowing

- Hives and difficulties in breathing
- Severe skin reactions that can include blistering of the skin.

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

If you experience a sudden decrease or loss of vision and hearing, stop taking Sildenafil citrate and contact your doctor immediately.

Tell your doctor promptly about these or any other unusual symptoms. If the symptoms persist or worsen, seek medical attention.

Frequent side effects may include:

- Flu symptoms, skin infection, inflammation in the stomach & small intestine
- Anaemia
- Fluid retention
- Inability to sleep, anxiety
- Headache, migraine, shakes, burning sensations, “pins and needles”, numbness
- Visual disturbances, increased eye redness, light-sensitivity, discolouration in the eye, eye irritation
- Spinning sensation
- Flushing
- Nose-bleeds, cough, nasal congestion
- Diarrhoea, acid reflux, piles, stomach cramps
- Night sweats, hair loss, redness of the skin
- Limb pain, muscle pain, back pain
- Enlargement of the breasts
- Fever
- Increase in weight

Less frequent side effects

- Double vision
- Bleeding from the penis, blood in the semen

Frequency unknown

- Low white blood cell count
- Increased thirst, increased acid in the joints (gout), unstable blood sugar levels, excess of watery fluid causing swelling
- Depression, increased sleepiness, abnormal dreams
- Impaired co-ordination, muscle stiffness, nerve pain, shakes, decreased reflexes, numbness, dizziness, fainting
- Dry eyes, sensitivity to light, eye infections, bleeding eyes, increased tearing of the eye, cataract, increased redness in the eye, loss of blood flow to the optic nerve of the eye, blockage of eye vessels, increased pressure in the eye, sensitivity to light, eye strain, blurry vision, irritation of the eye, dry and painful eyes, discolouration in the eye, loss of vision, retinal detachment (which may appear as tiny specks through your field of vision).
- Spinning sensation, ringing in the ears, inability to hear, ear pain
- Irregular and fast heartbeat, chest pain, abnormal ECG reading
- Low blood pressure
- Inability to breath, asthma, increased cough, increased mucus, tightness in the throat, dryness and swelling of the nose, throat infection, chest infection
- Dry mouth, diarrhoea, nausea, vomiting, stomach pain, bleeding gums, bleeding from the rectum, inability to eat, swelling of the food pipe, swelling of the stomach, abnormal liver function tests
- Rash, skin ulcers, redness, itching, peeling of the skin
- Joint and muscle pain, back pain, arthritis, bone pain, pain in the fingers and toes, torn tendons, inflamed joints
- Inability to control the bladder, bladder infection, blood in the urine
- Abnormal ejaculation, increased breast size, swelling of the genitals, inability to orgasm, prolonged erection
- Facial swelling, shock, tiredness, accidental fall, allergic reactions, chest pain, accidental injury

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 or 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 **MAKLITIO**.

5. How to store MAKLITIO

Store at or below 25 °C. Protect from light.

Keep the blisters in the carton until required for use.

Keep HDPE containers 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 pack and other information

What MAKLITIO contains

MAKLITIO 20 mg

The active ingredient in **MAKLITIO 20 mg** is Sildenafil Citrate equivalent to 20 mg active base.

Sugar- free.

Other ingredients include:

Croscarmellose sodium, Dibasic calcium phosphate dihydrate hypromellose, magnesium stearate, microcrystalline cellulose and film coating containing hypromellose, titanium dioxide and triacetin.

What MAKLITIO look like and contents of the pack

White to off white, round shaped, film coated tablets debossed with 'M7' on one side and plain on the other side.

HDPE container:

Round, white, HDPE container (30 ml) with 28 mm neck finish, containing 90 tablets, closed with white a polypropylene child resistant with pulp and heat seal liner and packed in a pre-printed unit carton.

Blister pack:

Clear 250 µ PVC/ 60 gsm PVdC as the forming material and silver coloured plain 25µ aluminium foil/ 6-8 gsm HSL as the lidding material, packed in a pre-printed unit carton.

Pack sizes 10s, 28s, 30s and 90s

Not all pack sizes will be marketed.

Holder of Certificate of Registration and Manufacturer

Macleods Pharmaceuticals SA (Pty) Ltd

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Alberton, South Africa.

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Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://www.macleodspharma.com> or email macleodsrsa@macleodspharma.com or contact 011 682 1169.