

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

MAKDEFIL 5 mg FC

Vardenafil hydrochloride equivalent to Vardenafil 5 mg

Sugar free.

MAKDEFIL 10 mg FC

Vardenafil hydrochloride equivalent to Vardenafil 10 mg

Sugar free.

MAKDEFIL 20 mg FC

Vardenafil hydrochloride equivalent to Vardenafil 20 mg

Sugar free.

MAKDEFIL 10 mg ODT

Vardenafil hydrochloride trihydrate equivalent to Vardenafil 10 mg

Contains sugar (48.20 mg of Lactose anhydrous) and Sweetener
(6 mg of Aspartame).

Read all of this leaflet carefully before you start taking MAKDEFIL

- 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.
- **MAKDEFIL** 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 **MAKDEFIL** is and what it is used for
2. What you need to know before you take **MAKDEFIL**
3. How to take **MAKDEFIL**
4. Possible side effects
5. How to store **MAKDEFIL**

6. Contents of the pack and other information

1. What MAKDEFIL is and what it is used for

MAKDEFIL and **MAKDEFIL 10 mg ODT** contains an ingredient called vardenafil hydrochloride, a member of a class of medicines called phosphodiesterase type 5 inhibitors.

They are prescribed for the treatment of erectile dysfunction in men. This is a condition where men have difficulties in achieving a penile erection hard enough for successful penetrative sex.

2. What you need to know before you take MAKDEFIL

Always tell your health care provider if you are taking any other medicine.

Your doctor should consider your cardiovascular status, since there is a degree of heart risk associated with sexual activity.

MAKDEFIL should not be used in men for whom sexual activity is not recommendable because of their underlying cardiovascular status. If sexual activity is not recommended for you due to some underlying heart condition, do not take **MAKDEFIL**.

Do not take MAKDEFIL:

- If you are hypersensitive (allergic) to vardenafil or any of the other ingredients of **MAKDEFIL** (listed in section 6)
- If you are concurrently treated with nitrates or nitric oxide donors.
- If you have ever had a condition involving loss of vision due to damage to the optic nerve from insufficient blood supply known as non-arteritic ischaemic optic neuropathy (NAION).
- If you are suffering from end-stage kidney disease requiring dialysis.
- If you are a woman or a child.
- If you are suffering from sickle cell anaemia, multiple myeloma or leukaemia.
- If you have anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease).
- If you are suffering from hypotension or low blood pressure (resting systolic blood pressure of < 90 mmHg).
- If you are suffering from uncontrolled hypertension or high blood pressure (> 170/110 mmHg).

- If you have a recent history of stroke, life-threatening irregular heart rhythm or heart attack (within last 6 months).
- If you are suffering from uncontrolled cardiac (heart) failure.
- If you suffer from unstable angina (chest pains as a result of lack of oxygen supply to the heart muscles).
- If there is a known hereditary (family related) degenerative eye disorders such as progressive degeneration of the retina.
- If you suffer from bleeding disorders.
- If you suffer from active peptic ulcers.
- If you suffer from severe impairment of liver function.
- If you are currently taking the HIV protease inhibitors indinavir and ritonavir.
- If you are over 75 years of age and are taking ketoconazole or itraconazole, anti-fungal medicines.
- You suffer from moderate hepatic impairment.
- You have phenylketonuria.
- You have hereditary problems of lactose intolerance.

If you are not at all sure, please consult your doctor.

Warnings and precautions

Talk to your doctor or health care provider before taking **MAKDEFIL**

Take special care with **MAKDEFIL**

Some loss of vision or blindness that is irreversible has been reported with some medication similar to **MAKDEFIL**. Should this occur, please consult your doctor immediately.

There have been reports of prolonged erections greater than 4 hours and priapism (painful erections greater than 6 hours in duration) for this class of medicines. In the event that your erection persists longer than 4 hours, you should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.

A sudden decrease or loss of hearing in one or both ears, with or without ringing in the ears and dizziness has been reported. You should contact your doctor as soon as you become aware of the hearing loss.

Use in children and patients younger than 18 years of age

MAKDEFIL is not to be used in children or adolescents under 18 years.

Other medicines and MAKDEFIL

Always tell your healthcare professional 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 **MAKDEFIL** with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare provider for advice.

It is particularly important that you tell your doctor or pharmacist if you are taking any of the following medicines:

- Alpha blockers, such as doxazosin, prazosin, phentolamine, used to treat high blood pressure and enlargement of the prostate (as benign prostatic hyperplasia).
- Nitrates (medicines for angina), or nitric oxide donors, such as amyl nitrite.
- Quinidine, procainamide, amiodarone or sotalol used to treat arrhythmias.
- Ketoconazole, itraconazole, clarithromycin, erythromycin, used to treat infections.
- Indinavir and ritonavir used for HIV treatment

The safety and efficacy of combinations of **MAKDEFIL** with other treatments for erectile dysfunction have not been studied, therefore, do not take **MAKDEFIL** in combinations with other erectile dysfunction medicines, unless if it is directed by your doctor.

MAKDEFIL with food and drink:

MAKDEFIL can be taken with or without food.

Do not drink grapefruit juice when you use **MAKDEFIL**. It can interfere with the usual effect of the medicine.

Pregnancy, breastfeeding and fertility

MAKDEFIL is not indicated for use by women.

Driving and using machines

MAKDEFIL may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

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

MAKDEFIL 10 mg ODT 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 medicinal product.

MAKDEFIL 10 mg ODT 10 mg contains Aspartame

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take MAKDEFIL

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

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

Take **MAKDEFIL** by mouth.

The usual dose is:

The recommended daily dose range is 5 mg, or 10 mg, or 20 mg per day. The recommended starting dose of **MAKDEFIL** is 10 mg. Based on efficacy and tolerability; your dose may be increased to 20 mg or decreased to 5 mg. The maximum recommended dose is 20 mg once daily.

MAKDEFIL 10 mg ODT is placed on the tongue and dissolves in the mouth in the presence of saliva. It should be taken immediately after release from the blister. It should be taken by itself without food or liquid in the mouth.

Take **MAKDEFIL** as needed (approximately one hour) before sexual activity.

However, you can take **MAKDEFIL** anytime from 25 minutes to at least up to 4 to 5 hours before sexual activity.

Do not take more than one (1) tablet of **MAKDEFIL** per day.

MAKDEFIL will not give you an instant erection; you will require sexual stimulation, either visual or physical, for an erection to occur after taking **MAKDEFIL**.

You should swallow the whole tablet with some liquid. It can be taken with or without food, according to your preference. Do not crush the tablets.

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

MAKDEFIL offers no protection against sexually transmitted diseases.

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

If you take more MAKDEFIL than you should

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

You may experience severe back pain if you have taken an overdose of **MAKDEFIL**.

In cases of overdose, your doctor or paramedics will take standard supportive measures as dictated by your clinical status.

4. Possible side effects

MAKDEFIL can have side effects.

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

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

-swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

- rash or itching

- fainting

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

If you experience sudden loss of vision while taking **MAKDEFIL**, you should stop treatment immediately and consult your doctor.

Tell your doctor if you notice any of the following:

Frequent side effects may include:

- headache
- dizziness
- flushing (vasodilation)
- blocked or runny nose
- indigestion (dyspepsia)

Less frequent side effects

- swelling of the skin and mucous tissue including swollen face, lips or throat
- sleep disorder
- “pins and needles” and unpleasant sensation (paraesthesia and dyesthesia), sleepiness
- visual disturbances, redness of eyes or watery eyes (ocular hyperaemia) ,
- sensitivity to light, colour distortion, eye pain and discomfort
- ringing of ears (tinnitus), feeling off balance (vertigo)
- palpitation, rapid heart rate (tachycardia)
- breathlessness (dyspnoea), stuffy nose (sinus congestion)
- nausea, stomach and abdominal pain, dry mouth, diarrhoea, acid reflux, gastritis,
- vomiting
- increase in protein enzymes (transaminases)
- inflammatory skin redness (erythema), rash
- back pain, increase in the enzyme creatine phosphokinase, increased muscle tone and

cramping, muscle pain (myalgia)

- increase in erection
- feeling unwell
- conjunctivitis
- allergic reaction
- fainting (syncope) loss of memory (amnesia), seizure
- increase in eye pressure (glaucoma)
- effects on the heart such as angina pectoris, heart attack (myocardial infarction),
- abnormal rapid heart rhythm that originates in the ventricles (ventricular tachyarrhythmias)
- low blood pressure
- prolonged and painful erection (priapism)
- chest pain
- nosebleed

Frequency unknown

- partial, sudden, temporary, or permanent loss in vision in one or both eyes
- sudden decrease or loss of hearing
- cerebral haemorrhage
- Bleeding from the penis, blood in semen (haemospermia)
- 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 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 **MAKDEFIL**.

5. How to store MAKDEFIL

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

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 pack and other information

What MAKDEFIL contains

The active ingredient in **MAKDEFIL** is Vardenafil hydrochloride equivalent to Vardenafil.

Other ingredients include:

Microcrystalline Cellulose (101), Crospovidone (Type A), Hypromellose 2910, Colloidal Silicon Dioxide, Magnesium Stearate VG-EP, Instacoat Orange A05G10191 which contains HPMC 2910/ Hypromellose, Polyethylene Glycol 400, Titanium Dioxide, Iron Oxide Red, Iron Oxide Yellow

What MAKDEFIL ODT mg 10 contains

The active ingredient in MAKDEFIL ODT 10 mg is Vardenafil hydrochloride Trihydrate equivalent to Vardenafil 10 mg

Other ingredients include:

Aspartame, Colloidal Silicon Dioxide (Aerosil 200), Crospovidone, (Polyplasdone XL), Lactose Anhydrous (Supertab 21 AN), Microcrystalline Cellulose (Avicel PH 102), Sodium Chloride, Sodium Stearyl Fumarate (Pruv) and Peppermint Flavour (501500TP0504) containing Maize maltodextrin, Natural flavours, E 1450 Modified corn starch and Pulegone

What MAKDEFIL looks like and contents of the pack

MAKDEFIL 5 mg FC:

Orange, round, film-coated tablets debossed with 'L 51' on one side and plain surface on the other side.

MAKDEFIL 10 mg FC:

Orange, round, film-coated tablets debossed with 'L 52' on one side and plain surface on the other side.

MAKDEFIL 20 mg FC:

Orange, round, film-coated tablets debossed with 'L 53' on one side and plain surface on the other side.

MAKDEFIL 10 mg ODT:

White to off white, round, biconvex, uncoated tablets debossed with 'T41' on one side and plain on other side.

MAKDEFIL 5 mg FC:

HDPE Container Pack: 30 tablets contained in a round white HDPE bottle sealed with a child resistant closure with pulp and heat seal liner.

Blister Pack: Tablets are packed in Clear film PVC/PVdC foil as the forming material and plain aluminium foil as the lidding material.

Pack size include 2's, 4's or 12's tablets.

MAKDEFIL 10 mg FC:

HDPE Container Pack: 30 tablets contained in a round white HDPE bottle sealed with a child resistant closure with pulp and heat seal liner.

Blister Pack: Tablets are packed in Clear film PVC/PVdC foil as the forming material and plain aluminium foil as the lidding material.

Pack size include 2's, 4's or 12's tablets.

MAKDEFIL 20 mg FC:

HDPE Container Pack: 30 tablets contained in a round white HDPE bottle sealed with a child resistant closure with pulp and heat seal liner.

Blister Pack: Tablets are packed in Clear film PVC/PVdC foil as the forming material and plain aluminium foil as the lidding material.

Pack size include 2's, 4's or 12's tablets.

MAKDEFIL 10 mg ODT:

Blister pack

Tablets are packed in cold form laminate, 25 µm OPA/45 µm Aluminum foil/60 µm PVC and Plain 30 µm Aluminum foil/6-8 gsm heat seal laquer (HSL) as the lidding material

Pack size: 1's, 2's, 4's and 10's.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Office Block 1, Bassonia Estate Office Park (East),

1 Cussonia Drive, Bassonia Rock, Ext. 12,

Alberton, South Africa.

This leaflet was last revised in

28 November 2023

Registration number

MAKDEFIL 5 MG FC: 51/7.1.5/9011

MAKDEFIL 10 MG FC: 51/7.1.5/9012

MAKDEFIL 20 MG FC: 51/7.1.5/9013

MAKDEFIL 10 MG ODT: 51/7.1.5/0538

Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://macleodssaproducts.co.za/> or contact 011 682 1169.