PATIENT INFORMATION LEAFLET

DYNAFIL RANGE

SCHEDULING STATUS

S4

DYNAFIL 25 mg tablets

DYNAFIL 50 mg tablets

DYNAFIL 100 mg tablets

Sildenafil

DYNAFIL contains sugar (lactose monohydrate) in the following quantities:

DYNAFIL 25 mg: 62,38 mg

DYNAFIL 50 mg: 124,76 mg

DYNAFIL 100 mg: 249,52 mg

Read all of this leaflet carefully before you start taking DYNAFIL

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

PATIENT INFORMATION LEAFLET

DYNAFIL RANGE

1. What DYNAFIL is and what it is used for

DYNAFIL belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) inhibitors.

It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited.

DYNAFIL will only help you to get an erection if you are sexually stimulated.

DYNAFIL is a treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep, a hard, erect penis suitable for sexual activity.

DYNAFIL IS NOT AN APHRODISIAC.

2. What you need to know before you take DYNAFIL

Do not take DYNAFIL:

- if you are hypersensitive (allergic) to sildenafil, or to any of the ingredients of DYNAFIL (see section 6)
- if you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure.

  Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
- if you are using any of the medicines known as nitric oxide donors (such as amyl nitrate), as the combination may also lead to a potentially dangerous decrease in your blood pressure
- if you have a severe liver or kidney disorder and are not receiving dialysis
- if you use erythromycin (antibiotic), ritonavir, saquinavir (for HIV infections), ketoconazole and itraconazole (treatment for fungal infections)
- if you are taking riociguat, a medicine used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). When taken with DYNAFIL, the blood

pressure lowering effects of riociguat are increased, if you are taking riociguate, or are unsure, talk to your doctor

- if you have recently had a stroke or a heart attack, suffer with chest pain that feels crushing, pressure-like, squeezing, or sharp (unstable angina) or if you have low blood pressure
- if you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION), a medical condition where the optic nerve is damaged due to loss of blood supply
- if you have certain rare inherited eye diseases (such as retinitis pigmentosa).

Warnings and precautions

Take special care with DYNAFIL:

- if you have had a heart attack or stroke or other life-threatening heart problems within the last 6 months, or have been told by a doctor that you are at risk of having a cardiac event
- if you have high or low blood pressure
- if you have any heart disorders such as angina. Your doctor will advise you as to whether your heart can take the additional strain of having sex
- if you have an eye disorder called retinitis pigmentosa (a hereditary disease, causing loss of vision)
- if you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow)
- if you have a deformity of your penis (or Peyronie's Disease) or are taking any other medicines for erectile dysfunction
- if you are taking medication known as alpha-blockers for hypertension (high blood pressure) or prostrate problems
- if you currently have a stomach ulcer, or a bleeding disorder (such as haemophilia)
- if you have a hearing problem or suddenly develop a hearing problem (symptoms may include dizziness, ringing in the ears or loss of balance) whilst taking DYNAFIL
- if you have eye disorders or experience sudden decrease or loss of vision.

If the latter happens, stop taking DYNAFIL and contact your doctor immediately

- if you suffer from any vision loss or a condition called ischaemic optic neuropathy as the use of DYNAFIL may worsen your condition
- if you are taking a medicine called ritonavir (used in the treatment of HIV) as this may affect the way DYNAFIL works.

You should not take DYNAFIL if you are a woman.

Other medicines and DYNAFIL

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

Medicines known to influence the effects of DYNAFIL are:

- certain anti-fungal medication (ketoconazole, fluconazole), certain antacid / ulcer medication (cimetidine), certain antibiotics (erythromycin, clarithromycin) and certain antiviral HIV medicines (ritonavir, saquinavir). These medicines may enhance the effects of DYNAFIL. Consult your doctor if you are taking any of these medicines
- mibefradil (to treat hypertension) and certain water tablets such as thiazides
- medicines used in the treatment of bleeding disorders (such as warfarin) or active peptic ulceration, DYNAFIL should be used with caution
- nicorandil (to treat chest pain)
- medicines used to treat depression including selective serotonin reuptake inhibitors (e.g. fluoxetine, paroxetine, sertraline, citalopram, escitalopram and fluvoxamine) and tricyclic antidepressants (e.g. doxepin, amitriptyline).

DYNAFIL tablets may interfere with the following:

- medicines used to treat chest pain. In the event of a medical emergency, you should tell any health care provider treating your condition that you have taken DYNAFIL and when you did

- medicines called nitrates, including nitric oxide as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or “chest pain”) (see Do not take DYNAFIL)
- medicines called antihypertensives (used to treat high blood pressure) as patients have experienced symptoms such as low blood pressure. This is most likely to occur within 4 hours after taking DYNAFIL. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your antihypertensive medicine before you start DYNAFIL. Your doctor may start you on a lower dose of DYNAFIL.

DYNAFIL with food and drink

Refrain from having grapefruit juice with DYNAFIL, as this may result in higher blood levels of DYNAFIL.

Pregnancy, breastfeeding and fertility

Do not take DYNAFIL if you are female.

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 DYNAFIL.

Driving and using machines

DYNAFIL can lead to dizziness and influence your vision.

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

DYNAFIL contains lactose

DYNAFIL contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take DYNAFIL.

DYNAFIL contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take DYNAFIL

Do not share medicines prescribed for you with any other person. Always take DYNAFIL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose of DYNAFIL will be different for different patients and may depend on the seriousness of your disorder and whether or not you are taking other medicines.

You should not take DYNAFIL more than once a day.

Adults:

The recommended dose is one 50 mg tablet per day when needed one hour before sexual intercourse.

Swallow the tablet whole with a glass of water.

Your doctor will tell you how long your treatment with DYNAFIL will last. If you have the impression that the effect of DYNAFIL is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNAFIL than you should

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

4. Possible side effects

Not all side effects reported for DYNAFIL are included in this leaflet. Should your general health

worsen, or if you experience any untoward effects while using DYNAFIL, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to DYNAFIL. 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, rapid heartbeat, high or low blood pressure
- swelling in any part of the body
- prolonged or painful erections
- sudden loss or decrease of vision
- sudden loss of hearing
- unstable diabetes
- seizures
- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters).

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:

- sleep disturbances including insomnia

- headache, dizziness, fever, flushing of the skin
- flu-like symptoms including throat infection, blocked or stuffy nose
- indigestion
- abnormal vision including blurred vision and colour tinge to vision.

Less frequent side effects:

- bladder infections, passing too little urine or more urine than is normal for you
- abnormal blood test results including anaemia and abnormal liver test results
- dry mouth, thirst
- depression, abnormal dreams (nightmares)
- migraine, feeling sleepy
- damage to the nerves of your legs and arms (such as numbness). pins and needles sensation
- light sensitivity, eye infection
- abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye
- ear pain, ringing in the ears
- asthma, cough, increased phlegm (mucous)
- nausea, vomiting, diarrhoea, abdominal pain
- bleeding from the rectum, traces of blood in your urine
- abnormal sweating, rash, itching or other skin reactions
- muscle, tendon, joint and back pain or inflammation
- muscle weakness, poor muscle coordination, tremors
- nose bleeds
- breast enlargement in men, prostrate disorder, abnormal ejaculation
- accidental injury and falls.

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. 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 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 DYNAFIL.

5. How to store DYNAFIL

Store all medicines out of reach of children.

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

Do not remove from outer carton until required for use.

Do not use after the expiry date stated on the carton. 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 DYNAFIL contains

The active substance is sildenafil.

DYNAFIL 25 mg: Each tablet contains sildenafil citrate equivalent to 25 mg sildenafil.

DYNAFIL 50 mg: Each tablet contains sildenafil citrate equivalent to 50 mg sildenafil.

DYNAFIL 100 mg: Each tablet contains sildenafil citrate equivalent to 100 mg sildenafil.

The other ingredients are:

Tablet cores:

Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone.

Coating - Opadry blue

Hypromellose 6cP, indigo carmine aluminium lake, Macrogol 6000, titanium dioxide

What DYNAFIL looks like and contents of the pack

DYNAFIL 25 mg: Blue, elliptical, biconvex, 10,0 x 5,0 mm film coated tablets, with SL25 engraved on one side.

DYNAFIL 50 mg: Blue, elliptical, biconvex, 13,0 x 6,5 mm film coated tablets, with SL50 engraved on one side.

DYNAFIL 100 mg: Blue, elliptical, biconvex, 17,0 x 8,5 mm film coated tablets, with SL100 engraved on one side.

DYNAFIL 25 mg is packed into hard, silver-coloured aluminium foil / transparent PVC/PVDC film blister strips, containing 2 or 4 tablets each. Each outer carton contains 1 blister strip.

DYNAFIL 50 mg is packed into hard, silver-coloured aluminium foil / transparent PVC/PVDC film blister strips, containing 2 or 4 tablets each. Each outer carton contains 1 blister strip.

DYNAFIL 100 mg is packed into hard, silver-coloured aluminium foil / transparent PVC/PVDC film blister strips, containing 2 or 4 tablets each. Each outer carton contains 1 blister strip.

Holder of Certificate of Registration

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15 March 2021

PATIENT INFORMATION LEAFLET

DYNAFIL RANGE

Registration number

DYNAFIL 25 mg: 42/7.1.5/1070*

DYNAFIL 50 mg: 42/7.1.5/1071

DYNAFIL 100 mg: 42/7.1.5/1072

*DYNAFIL 25 mg is currently not marketed in South Africa. Please use an alternative formulation if required.

DYNAFIL 50 mg: NAM: NS2 13/7.1.5/0086

DYNAFIL 100 mg: NAM: NS2 13/7.1.5/0087