PATIENT INFORMATION LEAFLET

TADALAFIL DYNA RANGE

SCHEDULING STATUS:

S4

TADALAFIL 5 mg DYNA film coated tablets

TADALAFIL 20 mg DYNA film coated tablets

Tadalafil

Contains lactose and sodium:

Each 5 mg film coated tablet contains 73,01 mg lactose (as monohydrate).

Each 20 mg film coated tablet contains 158,70 mg lactose (as monohydrate).

Each 5 mg film coated tablet contains 9,0 mg sodium (as sodium lauryl sulfate).

Each 20 mg film coated tablet contains 20,0 mg sodium (as sodium lauryl sulfate).

Read all of this leaflet carefully before you start taking TADALAFIL DYNA

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

PATIENT INFORMATION LEAFLET

TADALAFIL DYNA RANGE

1. What TADALAFIL DYNA is and what it is used for

TADALAFIL DYNA contains the active substance tadalafil.

TADALAFIL DYNA is a treatment for men with erectile disfunction. This is 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 TADALAFIL DYNA

Do not take TADALAFIL DYNA:

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of TADALAFIL DYNA (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
- if you have recently had a stroke within the last 6 months
- if you have low blood pressure or uncontrolled high blood pressure
- if have 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.

Take special care with TADALAFIL DYNA:

- 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 are taking other medication for erectile dysfunction as TADALAFIL DYNA should not be taken with certain other medicines (see section “Other medicines and TADALAFIL DYNA” below).

It is not known if TADALAFIL DYNA 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 nonnerve-sparing prostatectomy).

Children and adolescents

TADALAFIL DYNA is not intended for use by children and adolescents under the age of 18.

Other medicines and TADALAFIL DYNA

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).

TADALAFIL DYNA with food and drink

- TADALAFIL DYNA may be taken with or without food.
- grapefruit juice may affect how well TADALAFIL DYNA 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 TADALAFIL DYNA, 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

- TADALAFIL DYNA 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 TADALAFIL DYNA.

Driving and using machines

- you may experience dizziness while using TADALAFIL DYNA.
- it is not always possible to predict to what extent TADALAFIL DYNA may interfere with your daily activities
- you should ensure that you do not engage in the above activities until you are aware of the measure to which TADALAFIL DYNA affects you.

TADALAFIL DYNA 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.

TADALAFIL DYNA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film coated tablet 5 mg and 20 mg, that is to say essentially ‘sodium-free’.

3. How to take TADALAFIL DYNA

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

Always take TADALAFIL DYNA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

TADALAFIL 5 mg DYNA: The usual dose is one tablet daily, at the same time of day. TADALAFIL 5 mg DYNA and TADALAFIL 20 mg DYNA

- the maximum dose is 20 mg a day. TADALAFIL DYNA 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 TADALAFIL DYNA is too strong or too weak, tell your doctor or pharmacist.

If you take more TADALAFIL DYNA 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 TADALAFIL DYNA

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

4. Possible side effects

TADALAFIL DYNA can have side effects.

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

If any of the following happens, stop using TADALAFIL DYNA 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 allergic reaction to TADALAFIL DYNA. 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:

Frequent side effects:

- headache
- reddening of the face (flushing)
- stuffy nose
- discomfort in your stomach

- back pain, pain in your muscle or any part of your body

Less frequent side effects:

- 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 the 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 or pharmacist. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of TADALAFIL DYNA

5. How to store TADALAFIL DYNA

Store all medicines out of reach of children.

Store at or below 30°C.

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

Do not take tablets from the blister until required for use.

Keep blisters in 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 TADALAFIL DYNA contains

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

Each 5 mg film coated tablet contains 73,01 mg lactose (as monohydrate).

Each 20 mg film coated tablet contains 158,70 mg lactose (as monohydrate).

The other ingredients are:

Croscarmellose sodium, hydroxypropyl cellulose, Hydroxypropyl methylcellulose, lactose monohydrate, polyethylene glycol, magnesium stearate, microcrystalline cellulose, poloxamer, sodium lauryl sulfate, titanium dioxide, yellow ferric oxide.

What TADALAFIL DYNA looks like and contents of the pack

TADALAFIL DYNA 5 mg tablets are yellow, almond-shaped, biconvex, film-coated tablets engraved with T5 on one side and plain on the other side.

TADALAFIL DYNA 20 mg tablets are yellow, almond-shaped, biconvex, film-coated tablets engraved with T20 on one side and plain on the other side.

TADALAFIL DYNA 5 mg tablets are packed in PVC/Aclar clear film and aluminum foil, blisters of 10 tablets, then placed in an outer carton. Each carton contains 30 film-coated tablets.
TADALAFIL DYNA 20 mg tablets are packed in PVC/Aclar clear film and aluminium foil, blister of 2 or 4 tablets, then packed in an outer carton. Each carton contains 2 or 4 film-coated tablets.

HOLDER OF CERTIFICATE OF REGISTRATION

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

This leaflet was last revised in

Registration date: August 2022

Registration number

Tadalafil 5 mg Dyna: A49/7.1.5/0285

Tadalafil 20 mg Dyna: A49/7.1.5/0286