

**PATIENT INFORMATION LEAFLET
DYNAFIL range**

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DYNAFIL 25 mg coated tablets

DYNAFIL 50 mg coated tablets

DYNAFIL 100 mg coated tablets

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 or your pharmacist.
- **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.

1. WHAT DYNAFIL CONTAINS:

The active substance is sildenafil.

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

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

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

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The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry blue, povidone.

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).

2. WHAT DYNAFIL 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.

3. BEFORE YOU TAKE DYNAFIL:

Do not take DYNAFIL:

- if you are hypersensitive (allergic) to sildenafil, or any of the other ingredients of **DYNAFIL** (see **WHAT DYNAFIL CONTAINS**)
- 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

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- 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 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.

Take special care with DYNAFIL:

Tell your doctor if any of the following applies to you:

- 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

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- if you are taking medication known as alpha-blockers for hypertension (high blood pressure) or prostate 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 an elderly patient, follow the dose precisely as prescribed to you.

You should seek immediate medical assistance in the event of an erection that persists longer than 4 hours after taking **DYNAFIL**. Painful erections longer than 6 hours (priapism) should be treated immediately, as damage to the penis and permanent loss of potency could result.

You should not use **DYNAFIL** with any other oral or local treatments for erectile dysfunction, as this may cause side effects.

Prior to receiving **DYNAFIL**, the following will be discussed with you:

- **DYNAFIL** does not protect against sexually transmitted diseases, including HIV/AIDS. You should use protective measures necessary to guard against sexually transmitted diseases.

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- **DYNAFIL** could increase the risk for unwanted pregnancies.

Taking DYNAFIL with food and drink:

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

Pregnancy and breastfeeding:

Do not take **DYNAFIL** if you are female.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DYNAFIL**.

Driving and using machinery:

DYNAFIL can lead to dizziness and influence your vision and you should exercise caution before driving, operating hazardous machinery or performing hazardous tasks.

Important information about some of the ingredients of DYNAFIL:

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.

Taking other medicines with DYNAFIL:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines)

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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 healthcare professional 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**)

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- 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**.

4. HOW TO TAKE DYNAFIL:

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

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.

Always take **DYNAFIL** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

*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.

The dose can be increased or reduced the next day depending on the response. The maximum single dose per day is 100 mg.

Swallow the tablet whole with a glass of water.

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

If you take more DYNAFIL than you should:

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

5. POSSIBLE SIDE EFFECTS:

DYNAFIL can have 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 taking **DYNAFIL**, please consult your doctor, pharmacist or healthcare professional for advice.

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

- difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing
- severe itching of the skin (with raised lumps).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DYNAFIL**. You may require 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

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- prolonged or painful erections
- sudden loss or decrease of vision
- sudden loss of hearing
- unstable diabetes.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- 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:

- 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
- ear pain, ringing in the ears
- asthma, cough, increased phlegm (mucous)

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- 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.

6. STORAGE AND DISPOSING OF DYNAFIL:

Store at or below 25 °C.

Protect from light and moisture.

Do not remove from outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not use the tablets after the expiry date printed on the blisters and containers.

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