

**PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **Lafaval 20 mg filmomhulde tabletten**

#### **Tadalafil**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What [Product Name] is and what it is used for
2. What you need to know before you take [Product Name]
3. How to take [Product Name]
4. Possible side effects
5. How to store [Product Name]
6. Contents of the pack and other information

#### **1. What [Product Name] is and what it is used for**

[Product Name] contains the active substance tadalafil.

[Product Name] is a treatment for pulmonary arterial hypertension in adults.

It belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors which work by helping the blood vessels around your lungs relax, improving the flow of blood into your lungs. The result of this is an improved ability to do physical activity.

#### **2. What you need to know before you take [Product Name]**

##### **Do not take [Product Name] if you:**

- are allergic to tadalafil or any of the other ingredients (see section 6).
- are taking any form of nitrates such as amyl nitrite, used in the treatment of chest pain. Tadalafil has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.
- have ever had loss of vision – a condition described as “stroke of the eye” (non-arteritic anterior ischemic optic neuropathy - NAION).
- have had a heart attack in the last 3 months.
- have low blood pressure.

- are taking riociguat. This drug is 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). PDE5 inhibitors, such as tadalafil, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

### **Warnings and precautions**

Talk to your doctor before taking [Product Name].

Before taking the tablets, tell your doctor if you have:

- any heart problems other than your pulmonary hypertension
- problems with your blood pressure
- any hereditary eye disease
- an abnormality of red blood cells (sickle cell anaemia)
- cancer of the bone marrow (multiple myeloma)
- cancer of the blood cells (leukaemia)
- any deformation of your penis, or unwanted or persistent erections lasting more than 4 hours
- a serious liver problem
- a serious kidney problem.

If you experience sudden decrease or loss of vision, contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, contact your doctor immediately.

### **Children and adolescents**

[Product Name] is not indicated for use by children and adolescents under the age of 18.

### **Other medicines and [Product Name]**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do NOT take these tablets if you are already taking nitrates.

Some medicines may be affected by [Product Name] or they may affect how well [Product Name] will work.

Tell your doctor or pharmacist if you are already taking:

- bosentan (another treatment for pulmonary arterial hypertension)
- nitrates (for chest pain)
- alpha blockers used to treat high blood pressure or prostate problems.
- riociguat.
- rifampicin (to treat bacterial infections)
- ketoconazole tablets (to treat fungal infections)
- ritonavir (for HIV treatment)
- tablets for erectile dysfunction (PDE5 inhibitors).

### **[Product Name] with alcohol**

Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take [Product Name], avoid excessive drinking (over 5 units of alcohol), since this may increase the risk of dizziness when standing up.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not take [Product Name] when pregnant, unless it is strictly necessary and you have discussed this with your doctor.

Do not breastfeed while taking these tablets as it is not known if the medicine passes into human breast milk. Ask your doctor or pharmacist for advice before taking any medicine while pregnant or breastfeeding.

When dogs were treated there was reduced sperm development in the testes. A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility.

### **Driving and using machines**

Dizziness has been reported. Check carefully how you react to the medicines before driving or using any machinery.

**[Product Name] contains lactose.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **[Product Name] contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take [Product Name]**

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

[Product Name] is supplied as a 20 mg tablet. The usual dose is two 20 mg tablets taken once a day. You should take both tablets at the same time, one after the other. If you have a mild or moderate liver or kidney problem, your doctor may advise you to take only one 20 mg tablet per day.

Swallow the tablets whole with a drink of water. The tablets can be taken with or without food.

### **If you take more [Product Name] than you should**

If you or anyone else takes more tablets than they should, tell your doctor or go to a hospital immediately, taking the medicine or pack with you. You may experience any of the side effects described in section 4.

### **If you forget to take [Product Name]**

Take your dose as soon as you remember if it is within 8 hours of when you should have taken your dose. Do NOT take a double dose to make up for the one that you have forgotten.

### **If you stop taking [Product Name]**

Do not stop taking your tablets, unless advised otherwise by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate in nature.

**If you experience any of the following side effects stop using the medicine and seek medical help immediately:**

- allergic reactions including skin rashes (frequency common).
- chest pain - do not use nitrates, but seek immediate medical assistance (frequency common).
- priapism prolonged and possibly painful erection after taking [Product Name] (frequency uncommon). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (rarely reported).

The following side effects have been very commonly reported in patients taking tadalafil (may affect more than 1 in 10 people): headache, flushing, nasal and sinus congestion (blocked nose), nausea, indigestion (including abdominal pain or discomfort), muscle aches, back pain and pain in the extremity (including limb discomfort)

Other side effects have been reported:

##### **Common (may affect up to 1 in 10 people)**

- blurred vision, low blood pressure, nosebleed, vomiting, increased or abnormal uterine bleeding, swelling of the face, acid reflux, migraine, irregular heartbeat and fainting.

##### **Uncommon (may affect up to 1 in 100 people)**

- seizures, passing memory loss, hives, excessive sweating, penile bleeding, presence of blood in semen and/or urine, high blood pressure, fast heart rate, sudden cardiac death and ringing in the ears.

**PDE5 inhibitors** are also used for the treatment of erectile dysfunction in men. Some side effects have been rarely reported:

- Partial, temporary or permanent decrease or loss of vision in one or both eyes and serious allergic reaction which causes swelling of the face or throat. Sudden decrease or loss of hearing has also been reported.

Some side effects have been reported in men taking tadalafil for the treatment of erectile dysfunction.

These events were not seen in clinical studies for pulmonary arterial hypertension and therefore frequency is unknown:

- swelling of the eyelids, eye pain, red eyes, heart attack and stroke.

Most but not all of those men reporting fast heart rate, irregular heartbeat, heart attack, stroke and sudden cardiac death had known heart problems before taking tadalafil. It is not possible to determine whether these events were related directly to tadalafil.

#### **Reporting of side effects**

If you get any 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 directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store [Product Name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What [Product Name] contains

- The active substance is tadalafil.  
One film-coated tablet contains 20 mg tadalafil.
- The other ingredients are:

#### Tablet core

Lactose

Croscarmellose sodium (E468)

Sodium laurilsulfate (E487)

Hydroxypropylcellulose (E463)

Polysorbate 80 (E433)

Magnesium stearate

#### Coating

Hypromellose 2910 (E464)

Lactose monohydrate

Titanium dioxide (E171)

Triacetin (E1518)

Talc (E553b)

Iron oxide yellow (E172)

### What [Product Name] looks like and contents of the pack

Yellow colored, caplet shaped, biconvex, film-coated tablet, debossed with "T 20" on one side and plain on the other, with nominal dimensions 13.5 mm x 6.6 mm.

Available in blister packs containing 28, 30, 56 or 60 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Geneparm S.A.  
18th Km Marathonos Avenue  
Pallini 15351  
Griekenland

**Manufacturer**

Geneparm S.A.  
18th Km Marathonos Avenue  
Pallini 15351  
Griekenland

Pharmadox Healthcare Ltd.  
KW20A Kordin Industrial Park  
Paola, PLA 3000  
Malta

**In het register ingeschreven onder:**

RVG 129720

**This medicinal product is authorised in the Member States of the EEA under the following names:**

{Name of the Member State} {Name of the medicinal product}  
{Name of the Member State} {Name of the medicinal product}

**Deze bijsluiter is voor het laatst goedgekeurd in november 2023.**