

PATIENT INFORMATION LEAFLET

LONGIS® 20 mg Film-Coated Tablets

For oral use.

- **Active Substance:** Tadalafil
Each film-coated tablet contains 20 mg of tadalafil.
- **Excipients:** Lactose monohydrate (bovine source), croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, sodium lauryl sulfate, magnesium stearate, hypromellose, triacetin, titanium dioxide, yellow iron oxide, black iron oxide.

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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed specifically for you. Do not give it to others.*
- *When you visit a doctor or hospital, inform them that you are using this medicine.*
- *Follow the instructions exactly as described in this leaflet. Do not use a higher or lower dose than the one prescribed for you.*

This Package Leaflet contains:

1. *What is LONGIS® and what is it used for?*
2. *What should be considered before using LONGIS®?*
3. *How to use LONGIS®?*
4. *What are the possible side effects?*
5. *How to store LONGIS®?*

1. What is LONGIS® and what is it used for?

LONGIS® is available in blister packs containing 2 or 4 film-coated tablets. These tablets are yellow, convex, round, and have a "T20" logo on one side.

LONGIS® is a medication used for the treatment of erectile dysfunction in adult men. Erectile dysfunction is a condition where it is impossible to achieve or maintain the penile erection necessary for sexual activity. It has been shown that LONGIS® significantly improves the ability to achieve suitable penile erection for sexual activity.

LONGIS® contains the active substance tadalafil, and it belongs to a group of medications called phosphodiesterase type 5 (PDE5) inhibitors. Following sexual stimulation, LONGIS®

helps relax the blood vessels in the penis, allowing blood to flow into the penis. As a result, an erection occurs. LONGİS® will not work if you do not have an erection problem.

It is important to note that in the absence of sexual stimulation, LONGİS® will not work on its own. Therefore, you and your partner should engage in foreplay as if you were not taking medication for erectile dysfunction.

2. What should you consider before using LONGİS®?

DO NOT use LONGİS® if you:

- Are allergic to tadalafil or any other ingredients in LONGİS®.
- Are using any form of organic nitrates or amyl nitrites, which contain nitric oxide. These drugs (nitrates) are used in the treatment of chest pain (angina pectoris) related to coronary heart disease. LONGİS® has been shown to enhance the effects of these drugs. If you are using any form of nitrates or are unsure, inform your doctor.
- Have a serious heart condition or have had a heart attack in the last 90 days.
- Have unstable chest pain or experience chest pain during sexual activity.
- Have had "Class 2" or more severe heart failure as classified by the New York Heart Association in the past 6 months.
- Have uncontrolled heart rhythm problems (arrhythmias).
- Have very low blood pressure (<90/50 mm Hg) or uncontrolled high blood pressure.
- Have had a stroke in the last 6 months.
- Have experienced vision loss due to non-arteritic anterior ischemic optic neuropathy (NAION), also known as eye stroke.
- Are using riociguat. This medication is used to treat pulmonary arterial hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs caused by blood clots). It has been shown that PDE5 inhibitors like LONGİS® can increase the blood pressure-lowering effects of riociguat. If you are using riociguat or are unsure, consult your doctor.

USE LONGİS® WITH CAUTION if you:

Before using LONGİS®, talk to your doctor.

Since sexual activity puts extra strain on your heart, it may pose a potential risk for patients with heart conditions. Therefore, if you have a heart problem, you should inform your doctor.

The following reasons indicate why LONGİS® may not be suitable for you. If any of these apply to you, please consult your doctor before taking the medication:

- Abnormalities in red blood cells (sickle cell anemia), bone marrow cancer (multiple myeloma), blood cell cancer (leukemia), or if you have a deformity in your penis.
- Severe liver problems.
- Severe kidney problems.
- Frequent and prolonged erections in the penis without sexual desire.

- It is not known whether LONGİS® is effective in patients who have undergone pelvic surgery, such as radical prostatectomy, where the nerve that surrounds the prostate gland is not preserved.

If you experience a sudden decrease in vision, vision loss, or visual disturbances while using LONGİS®, stop using it immediately and consult your doctor.

If any of the above warnings apply to you, even in the past, please consult your doctor. Some patients using tadalafil have reported a decrease or sudden loss of hearing. Although it is not known whether this is directly related to tadalafil, if you experience hearing loss or sudden hearing impairment, stop using LONGİS® immediately and consult your doctor. LONGİS® is not intended for use by women or males under the age of 18.

LONGİS® and Food or Drink:

You can take LONGİS® with or without food.

Please refer to Section 3 for the effects of alcohol when used with LONGİS®. Grapefruit juice may affect the effect of LONGİS® and should be used with caution. For more information, talk to your doctor.

Pregnancy:

Not applicable.

In animal studies, a decrease in sperm development in the testes was observed when dogs were treated. A decrease in sperm count has been seen in some men. However, these effects are unlikely to cause infertility.

Breastfeeding:

Not applicable.

Fertility:

In studies on dogs, a decrease in sperm development in the testes was observed. Some men have also experienced a decrease in sperm count. However, these effects are unlikely to lead to infertility.

Driving and Machine Use:

In clinical studies, some men using LONGİS® have reported dizziness. Therefore, it is important to know how you respond to the medication before driving or operating machinery.

Important Information about Some of the Ingredients in LONGİS®:

LONGİS® contains lactose derived from cows. If you have been told by your doctor that you cannot tolerate certain sugars, please consult your doctor before taking this medicine.

Use of LONGİS® with Other Medications:

It is very important to inform your doctor or pharmacist, especially if you are being treated with nitrates, as you should not use LONGİS® with nitrates.

If you are using any of the following medications together with LONGİS®, please inform your doctor or pharmacist as LONGİS® or the listed medications may be affected:

- Non-selective alpha blockers (commonly used to treat high blood pressure or urinary symptoms associated with benign prostate enlargement).
- Other medications used to treat high blood pressure.
- Riociguat.
- 5-alpha reductase inhibitors (used for the treatment of an enlarged prostate).
- Medications like ketoconazole (used for fungal infections) and protease inhibitors for the treatment of AIDS or HIV infection.
- Phenobarbital, phenytoin, and carbamazepine (used to treat seizures).
- Rifampicin, erythromycin, clarithromycin, or itraconazole (used to treat bacterial and fungal infections).
- Other medications used to treat erectile dysfunction.

If your doctor has told you not to use certain medications, do not take LONGİS® with them.

If you are undergoing treatment for erectile dysfunction, do not use LONGİS® with other such medications.

If you are currently taking or have recently taken any prescription or over-the-counter medications, please inform your doctor or pharmacist about them.

3. How to use LONGİS®**Instructions for proper use and dosage/application frequency:**

Always take LONGİS® exactly as your doctor has instructed. If you are unsure, consult your doctor or pharmacist.

Generally, the recommended dose is 10 mg, taken at least 30 minutes before the planned sexual activity. For patients in whom 10 mg tadalafil does not show sufficient effect, the dose may be increased to 20 mg.

A maximum of one dose per day should be used.

Tadalafil doses of 10 mg or 20 mg should be taken before the planned sexual activity and are not recommended for continuous daily use.

For products containing 20 mg tadalafil (excluding scored tablets), it is not appropriate to divide the tablet.

LONGIS® can remain effective for up to 36 hours after taking the tablet. You should be aware that LONGIS® will not work in the absence of sexual stimulation. Therefore, you and your partner should engage in foreplay, as if not taking medication, for the treatment of erectile dysfunction.

Alcohol consumption may negatively affect your ability to achieve an erection. Alcohol intake can temporarily lower your blood pressure. If you have taken or plan to take LONGIS®, avoid excessive alcohol consumption (blood alcohol level should not exceed 0.08%), as this can increase the risk of dizziness when standing up.

Method of administration:

LONGIS® tablets are for oral use only in men. Swallow the tablet whole with some water. LONGIS® can be taken with or without food.

Different age groups:

Use in children:

LONGIS® is not suitable for use in children or adolescents under the age of 18.

Special usage conditions:

There are no special usage conditions.

If you feel that the effect of LONGIS® is too strong or too weak, consult your doctor or pharmacist.

If you have taken more LONGIS® than you should:

If you have taken more LONGIS® than you should, contact your doctor or pharmacist. You may experience the side effects listed in Section 4.

If you forget to take LONGIS®:

Take your dose as soon as you remember, but do not take a double dose to make up for a missed dose.

If you have any other questions about the use of this product, consult your doctor or pharmacist.

Effects when treatment with LONGIS® is discontinued:

None known.

4. What are the possible side effects?

Like all medicines, LONGIS® may cause side effects in people who are sensitive to the ingredients. These side effects are usually mild to moderate.

The side effects listed in this leaflet are categorized as follows:

Very common: May affect more than 1 in 10 people.

Common: May affect up to 1 in 10 people.

Uncommon: May affect up to 1 in 100 people.

Rare: May affect up to 1 in 1,000 people.

Very rare: May affect up to 1 in 10,000 people.

Unknown: Cannot be estimated from the available data.

If you experience any of the following, stop using LONGİS® and IMMEDIATELY contact your doctor or go to the nearest hospital emergency department:

- Allergic reaction (including rash) (frequency: uncommon)
- Chest pain – Do not use nitrates, seek medical help immediately (frequency: uncommon)
- Prolonged and painful erection (priapism) after using LONGİS® (frequency: rare). If you experience an erection lasting more than 4 hours, seek immediate medical attention.
- Sudden loss of vision (frequency: rare), visual disturbances, darkened vision, blurred central vision, or sudden decrease in vision (frequency: unknown).

Other reported side effects:

Common side effects (may affect more than 1 in 100 people but less than 1 in 10 people):

Headache, back pain, muscle aches, arm and leg pain, flushing (redness of the face), nasal congestion, indigestion.

Uncommon side effects (may affect more than 1 in 1,000 but less than 1 in 100 people):

Dizziness, stomach pain, nausea, vomiting, acid reflux, blurred vision, eye pain, difficulty breathing, blood in the urine, prolonged erection, palpitations, rapid heartbeat, high blood pressure, low blood pressure, nosebleeds, ringing in the ears, swelling in the hands, feet, and ankles, and feeling tired.

Rare side effects (may affect more than 1 in 10,000 but less than 1 in 1,000 people):

Fainting, seizures, temporary memory loss, eyelid swelling, red eyes, sudden hearing decrease or loss, hives (itchy red rash on the skin), blood in the urine, blood in semen, and increased sweating.

Heart attack and stroke have been reported in men using LONGİS®. Most of these men had pre-existing heart conditions before using the medication.

Partial, temporary, or permanent reduction in vision ability or vision loss in one or both eyes has been reported rarely.

Other rare side effects observed in men using LONGİS® in clinical trials include:

Migraine, swelling of the face, severe allergic reactions causing swelling of the face or throat, skin redness, disorders affecting blood flow to the eyes, irregular heartbeat, angina, sudden

cardiac death, visual disturbances, darkened vision, blurred central vision, or sudden vision loss (frequency: unknown).

In men aged 75 and older, dizziness has been reported more frequently as a side effect of LONGİS®. In men aged 65 and older, diarrhea has been reported more frequently.

If you experience any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting side effects:

If you experience any side effects listed or not listed in this leaflet, consult your doctor, pharmacist, or nurse. You can also report side effects by clicking on the “Drug Side Effect Notification” icon on the website www.titck.gov.tr or by calling the 0 800 314 00 08 side effect notification hotline to report to the Turkish Pharmacovigilance Center (TÜFAM). By reporting side effects, you will contribute to further knowledge about the safety of the medication you are using.

5. Storage of LONGİS®

Store LONGİS® in a place where children cannot see or reach.

LONGİS® film-coated tablets should be stored in their original packaging to protect them from moisture, at room temperature below 25°C.

Use in accordance with the expiration date.

Do not use LONGİS® after the expiration date on the packaging.

Do not throw expired or unused medication in the trash! Dispose of it through the collection system specified by the Ministry of Environment, Urbanization, and Climate Change.

If you notice any damage to the product and/or packaging, do not use LONGİS®.

Marketing Authorization Holder:

Santa Farma Ilac San. A.S.

H. Edip Adivar/ Borucicegi Sokak. No: 16 Sisli- Istanbul, Turkey

Tel: 0212 220 64 00

Faks: 0212 222 57 59

Manufacturer:

Kocaeli, Gebze, V (Kimya) Ihtisas OSB Erol Kiresepi Cad. No: 8, Dilovası, Kocaeli, Turkey

Tel: (+90 262) 674 23 00

Fax: (+90 262) 674 23 21

This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]