

PATIENT INFORMATION LEAFLET

TALDEROL® 90 mg film coated tablet

Administered orally.

- **Active Ingredient:** Each tablets contains 90 mg ticagrelor
- **Excipients:** Mannitol (E421), dibasic calcium phosphate dihydrate, microcrystalline cellulose pH 101, hydroxypropyl cellulose, croscarmellose sodium, colloidal silica hydrate 244, magnesium stearate, hypromellose, titanium dioxide, talc, polyethylene glycol 400, yellow 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, ask to your doctor or pharmacist.*
- *This medicine has been prescribed for you only; do not share it with another person.*
- *During the usage of this drug, when you visit the doctor or the hospital, inform your doctor about this.*
- *Respect the instructions given to you about your drug. Do not use a dose above or below the dose prescribed for you.*

In This Leaflet:

1. **What is TALDEROL® and what is used ?**
2. **What you need to know before you take TALDEROL® ?**
3. **How to take TALDEROL®?**
4. **Possible side effects?**
5. **How to store TALDEROL®**

Sections are presented.

1. What is TALDEROL® and what is used?

- TALDEROL® is a medicine containing the active ingredient ticagrelor. It belongs to a group of medicines called antiplatelet agents (which prevent blood clotting).
- TALDEROL® is a yellow, round, biconvex film-coated tablet. It is available in blister packs of 56 and 168 tablets.
- TALDEROL® is used only in adults, in combination with acetylsalicylic acid (other antithrombotic drug) or alone after the first 3 months of use with acetylsalicylic acid.

The reason why this medicine was given to you;

- you have had a heart attack or
- you have unstable angina (chest pain or angina that is not well controlled).

- TALDEROL® reduces your risk of having another heart attack or stroke, or of dying from a disease related to your heart or blood vessels. TALDEROL® affects cells called platelets (clotting cells). These tiny blood cells cluster together to fill tiny holes in cut or damaged blood vessels, helping stop bleeding.

However, platelets can form clots in diseased blood vessels in the heart and brain. This situation can be very dangerous; Because:

- The clot can completely cut off blood flow; This can cause heart attack (myocardial infarction) or stroke.
- The clot can partially block the blood vessels leading to the heart; This reduces blood flow to the heart, which can cause chest pain that comes and goes (called “unstable angina”).

TALDEROL® helps stop the clumping of clotting cells. This reduces the chance of blood clots forming, which can block blood flow.

2. What you need to know before you take TALDEROL®

DO NOT USE TALDEROL

- If you are allergic (hypersensitive) to ticagrelor or any other excipients of TALDEROL®,
- If you have active bleeding,
- If you have had a stroke caused by brain bleeding,
- If you have serious liver disease,
- If you are using any of the following medicines:
 - Ketoconazole (used to treat fungal infections),
 - Clarithromycin (used in the treatment of bacterial infections),
 - Nefazodone (used to treat depression),
 - Ritonavir and atazanavir (used in the treatment of HIV infections and AIDS).

If any of the above mentioned occur in you, do not use TALDEROL®. If you are not sure, consult your doctor or pharmacist before taking the medicine.

TAKE SPECIAL CARE WITH TALDEROL®

- If you have a high risk of bleeding due to one of the following conditions:
 - If you have recently suffered a significant injury,
 - If you have recently had a surgical intervention (including dental treatment, consult your dentist about this),
 - If you have a disease that affects blood clotting,
 - If you have recently had stomach or intestinal bleeding (such as a stomach ulcer or intestinal “polyps”).
- If you need to undergo surgery (including dental treatment) at any time while using TALDEROL®. This is because the risk of bleeding increases. Your doctor may ask you to stop taking this medicine 5 days before surgery.
- Your heart rate is abnormally slow (usually less than 60 beats per minute) and you do not have a pacemaker.
- If you have asthma or other lung problems or breathing difficulties,
- You develop irregular breathing patterns, such as quickening, slowing down, or brief pauses in breathing. Your doctor will decide whether you need further evaluation.
- If you have had any problems with your liver or have ever had a disease that affects your liver,

- If your blood test shows that you have a higher than normal amount of uric acid in your blood, If these warnings apply to you, even at any time in the past, please consult your doctor.

If you are taking both TALDEROL® and heparin:

- If your doctor suspects a rare platelet disorder caused by heparin, he or she may need a blood sample for diagnostic tests. It is important to inform your doctor that you are taking both TALDEROL® and heparin, as TALDEROL® may affect diagnostic testing.

Using TALDEROL® with food and drink

You can take TALDEROL® with or without food.

Exposure to TALDEROL® increases 2-fold after consuming large amounts (3x200 ml) of grapefruit juice each day. This increase has no clinical significance.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

There are no sufficient data on the use of ticagrelor in pregnant women. Studies on animals have shown that it has toxic effects on reproduction. The potential risk to humans is unknown.

It is not recommended to use TALDEROL® if you are pregnant or may be pregnant. Use appropriate birth control methods to avoid becoming pregnant while using TALDEROL®.

If you are pregnant, may be pregnant, or are planning to become pregnant, consult your doctor or pharmacist before using TALDEROL®.

TALDEROL® should not be used during pregnancy unless necessary.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast Feeding

Ask your doctor or pharmacist for advice before taking this medicine

TALDEROL® products formed in the body pass into milk.

Studies conducted in animals have shown that ticagrelor and its active by-products formed after exposure to the body pass into milk. This risk for newborns/infants cannot be ignored.

Before using TALDEROL®, tell your doctor that you are breast-feeding. Your doctor will explain to you the benefits and risks of using TALDEROL® during this period. A decision must be made whether to discontinue breast-feeding or discontinue/avoid TALDEROL® treatment

Driving and using machine

TALDEROL® is not expected to affect your ability to drive or use machines. If you experience drowsiness or confusion while using TALDEROL®, you should be careful when driving or operating machinery.

Important information regarding some excipients in TALDEROL®

TALDEROL® contains mannitol as an excipient and no warning is required due to its quantities.

Taking with other drugs

Tell your doctor or pharmacist about any other medications you have recently taken or are taking. Because TALDEROL® may affect the working mechanism of some drugs and some drugs may also have an effect on TALDEROL®

Inform your doctor or pharmacist if you are using any of the following medications:

- More than 40 mg of simvastatin or lovastatin (drugs used to treat high cholesterol) per day,
- Rifampicin (an antibiotic),
- Phenytoin, carbamazepine and phenobarbital (used to control epilepsy seizures),
- Digoxin (used in the treatment of heart failure),
- Cyclosporine (used to weaken body defenses),
- Quinidine and diltiazem (used to treat abnormal heart rhythms),
- Beta blockers and verapamil (used to treat high blood pressure),
- Morphine and other opioids (used to treat severe pain),
- Levonorgestrel, ethinyl estradiol (used in birth control).

Be sure to inform your doctor or pharmacist if you are using any of the following medications, especially those that increase your risk of bleeding:

- “Oral anticoagulants”, which include warfarin and are often called “blood thinners”,
- Nonsteroidal anti-inflammatory drugs (abbreviated as NSAIDs), such as ibuprofen and naproxen, which are generally taken as painkillers and antipyretics,
- Selective serotonin reuptake inhibitors (abbreviated as SSRIs), taken as antidepressants (effective against depression), such as paroxetine, sertraline and citalopram,
- Ketoconazole (used to treat fungal infections), clarithromycin (used to treat bacterial infections), nefazodone (an antidepressant medicine), ritonavir and atazanavir (used to treat HIV infection and AIDS), cisapride (used to treat heartburn), ergot alkaloids (migraine and headache). Other medicines such as: used to treat pain.

If you are taking or have recently taken any other medicines including medicines obtained with or without a prescription, please tell your doctor or pharmacist.

3. How to take TALDEROL®

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

Instructions for proper use and dosage/frequency of administration:

- The starting dose is to take 2 tablets at the same time (loading dose 180 mg). This dose is usually given to you in hospital.
- Following the initial dose, the general dosage is one 90 mg tablet twice a day for 12 months unless your doctor specifies a different period.
- Take your medicine at approximately the same time every day (for example, 1 tablet in the morning, 1 tablet in the evening).

Your doctor will usually tell you to also take low-dose acetylsalicylic acid (aspirin). This substance is found in many medications used to prevent blood clotting. Your doctor will tell you how much you should take (usually between 75-150 mg per day).

Route and method of application:

- You can take the medicine with food or on an empty stomach.
- You can check the date of the last TALDEROL® tablet you took by looking at the blister..

If you have problems swallowing the tablet:

- If you have trouble swallowing the tablet, you can break the tablet and mix it with water by following the instructions below:
- Break the tablet and grind it into fine powder.
- Throw the powdered tablet into half a glass of water.
- Mix and drink without waiting.
- To make sure that there is no medicine left at the bottom, rinse the empty glass with half a glass of water and drink it

If you are in hospital, you may be given this tablet mixed with some water and given through a tube through your nose (nasogastric).

Different age groups:

Use in children:

TALDEROL® is not recommended for use in children and young people under the age of 18.

Use in the elderly:

There is no need for dose adjustment in the elderly.

Special use cases:

Kidney failure:

There is no need for dose adjustment in renal failure.

It is recommended that patients undergoing dialysis do not use TALDEROL®.

Liver failure:

There is no need for dose adjustment in mild or moderate hepatic impairment. TALDEROL® should not be used in patients with severe hepatic impairment. Caution should be exercised in patients with moderate hepatic impairment.

If you think that the effect of TALDEROL® is very strong or very poor, please tell your doctor or pharmacist.

If you use more TALDEROL® than you should:

You may have a high risk of bleeding.

If you have used more than necessary to use from TALDEROL®, please tell your doctor or pharmacist or contact nearest hospital emergency department immediately..

If you forget to take TALDEROL®

If you forget to take a dose, take your next dose at the time you are supposed to take it.

Do not take a double dose to make up for the forgotten dose.

Effects that may occur when treatment with TALDEROL® is stopped:

Do not stop taking TALDEROL® without talking to your doctor. Continue to use this medicine regularly as long as your doctor prescribes it. If you stop taking TALDEROL®, your risk of having another heart attack or stroke may increase, or your risk of death from a disease related to your heart or blood vessels.

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

3. Possible Side Effects ?

Like all medicines, side effects may occur in people who are sensitive to the ingredients contained in TALDEROL®. The following side effects may occur during the use of this medicine:

Since TALDEROL® affects blood clotting, most side effects are related to bleeding. Bleeding can occur in any part of your body. Some bleeding (such as bruising and nosebleeds) is common. Serious bleeding is uncommon but can be life-threatening.

The side effects are listed as shown in the following categories:

Very common:	may be affected in more than one patient from 10
Common:	may be affected in 1-10 patients from 100
Uncommon:	may be affected in 1-10 patients from 1000
Rare:	may be affected in 1-10 patients from 10000
Unknown:	cannot be estimated from the available data

If any of the following occur, stop using TALDEROL® and IMMEDIATELY inform your doctor or go to the emergency department of your nearest hospital:

• **Bleeding within the brain or skull is an uncommon side effect and may cause the following stroke symptoms:**

- Sudden numbness or numbness in your arms, legs or face (especially if it is only on one side of your body)
- Sudden dizziness, difficulty speaking or understanding others
- Sudden difficulty walking, loss of balance or coordination
- Sudden dizziness or sudden severe headache with no known cause

• **The following signs of bleeding:**

- Severe or uncontrollable bleeding
 - Unexpected bleeding or prolonged bleeding
 - Pink, red or brown urine
- Vomiting red blood or your vomit looking like “coffee grains”
- Red or black stools (looking like tar)
 - Blood clot coming from coughing or vomiting

• **Fainting (syncope):**

- Temporary loss of consciousness due to sudden decrease in blood flow to the brain (common)

• **Symptoms of a blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP)**

- Fever and purplish spots on the skin or mouth (called purpura), with or without yellowing of the skin or eyes (jaundice), unexplained extreme tiredness or confusion.

These are all very serious side effects. If you have any of these, you may need urgent medical attention or hospitalization.

If you experience any of the following, tell your doctor:

- **Feeling short of breath – very common.** This may be caused by your heart condition or another cause, or it may be a side effect of TALDEROL®. Breathlessness associated with TALDEROL® is usually mild and is characterized by sudden, unexpected air hunger that often occurs at rest and occurs during the first weeks of treatment, most of which disappears. If your shortness of breath gets worse or lasts longer, tell your doctor. Your doctor will decide whether treatment or more comprehensive examination is needed.

Other possible side effects:

Very common:

- Kanınızda yüksek ürik asit düzeyi (testlerde görüldüğü üzere)
- Kan hastalıklarının neden olduğu kanamalar

Common

- Low blood pressure (hypotension)
- Respiratory system bleeding (bloody sputum hemoptysis)
- Bruising

- Headache
- Feeling lightheaded or like the room is spinning
- Diarrhea or indigestion
- Feeling sick (nausea)
- Constipation
- Bleeding under the skin or on the skin
- Itching
- Rash
- Severe pain and swelling in your joints – these are symptoms of gout.
- Feeling dizzy or lightheaded or blurred vision – these are signs of low blood pressure.
- Nose bleeding
- Bleeding after surgery or after a cut (e.g. while shaving) and bleeding more than normal from the wound - post-traumatic bleeding
- Stomach bleeding (ulcer)
- Bleeding in the gums
- Bleeding in the urinary tract
- Increase in blood creatinine level, which shows whether the kidneys are working regularly or not
- Fainting (syncope)

Uncommon

- Tumor bleeding (bladder cancer, gastric cancer and colon cancer)
- Confusion
- Vision problems due to bloodshot eyes
- Vaginal bleeding that is more severe or occurs at different times than your normal menstrual bleeding
- Bleeding that causes painful swelling in your joints and muscles
- Bleeding in your ear
- Internal bleeding may cause dizziness or lightheadedness.
- Hypersensitivity, including swelling of the face and throat as a result of allergies
- Reproductive system bleeding
- Intracranial bleeding (intracranial hemorrhage)
- Bleeding in the outer or posterior membrane of the abdominal membrane (retroperitoneal hemorrhage)

Frequency unknown

- Abnormally low heart rate (usually less than 60 beats per minute)

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

Reporting side effects

If you experience any side effects, whether listed in the Instructions for Use or not, talk to your doctor, pharmacist or nurse. Also, report side effects to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Reporting" icon on the website www.titck.gov.tr or by calling the side effect reporting line at 0 800 314 00 08. By reporting any side effects that occur, you will contribute to obtaining more information about the safety

of the medicine you are using.

4. How to store TALDEROL®

Keep out of TALDEROL® sight and reach of children in its original packaging.

Store below 25 °C.

Use within shelf life.

Do not use TALDEROL® after the expiry date which is stated on the package/outer box.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Marketing Authorization Holder:

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