

PATIENT INFORMATION LEAFLET

CALBICOR® 6.25 mg tablets

For oral administration.

- **Active ingredient:** Each tablet contains 6.25 mg of carvedilol.
- **Excipients:** Bovine lactose monohydrate (spray dried), corn starch, sodium lauryl sulfate, magnesium stearate, croscarmellose sodium, colloidal silicon dioxide, 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 your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Please tell your doctor that you are taking this medicine if you seek medical assistance during the use of this medicine.*
- *Follow these instructions carefully. Do not take **higher or lower** doses than recommended.*

What is in this leaflet:

- 1. What is CALBICOR® and what is it used for?**
- 2. Before using CALBICOR®, what should be considered**
- 3. How to use CALBICOR®**
- 4. What are the possible side effects of CALBICOR®.**
- 5. Storage of CALBICOR®**

Titles are included.

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

CALBICOR®, contains an active ingredient called carvedilol. This belongs to a group called "beta-blockers."

CALBICOR® is available in blister packs containing 30 tablets. The tablets are round, slightly convex, and light yellow in color, with one side scored and the other side bearing the C2 logo.

CALBICOR® is used in the treatment of the following conditions:

- High blood pressure (hypertension)
- Angina (chest pain or discomfort that occurs when your heart doesn't get enough oxygen)
- Chronic heart failure

Your doctor may prescribe other medications in addition to CALBICOR® to treat your condition.

CALBICOR® contains bovine lactose monohydrate.

2. Before using CALBICOR® please pay attention to the following

Do NOT use CALBICOR® in the following situations

If:

- You are allergic to carvedilol or any of the ingredients in CALBICOR®.
- You have wheezing in your chest due to asthma or other lung diseases.
- You are experiencing severe fluid retention treated with intravenous medications (swelling of hands, wrists, and feet).
- You have liver disease.
- You have heart problems (such as heart block or slowed heart rate). CALBICOR® is less suitable for individuals with certain types of heart conditions.
- Your blood pressure is low.
- You have metabolic acidosis (high acid levels in your blood).
- You have growths on your adrenal glands (pheochromocytoma).

Use CALBICOR® with caution in the following situations

If:

- You have kidney problems.
- You have diabetes (high blood sugar).
- You wear contact lenses.
- You have had thyroid problems in the past.
- You have experienced severe allergic reactions (such as sudden body swelling leading to difficulty breathing and swallowing, swelling of hands, feet, and ankles, severe rash).
- You have allergies and are undergoing treatment that makes you sensitive.
- You have circulation problems in your fingers and toes (Raynaud's phenomenon).
- You have had psoriasis (a skin condition) after taking beta-blockers.
- You develop serious skin reactions such as Stevens-Johnson syndrome (skin peeling, swelling, blisters, and fever) and toxic epidermal necrolysis (severe skin reactions with fluid-filled blisters and tissue loss).

If any of these warnings apply to you, even if they have applied in the past, please consult your doctor.

Use of CALBICOR® with food and drinks

CALBICOR® should be taken with water. In patients with chronic heart failure, CALBICOR® should be taken with food.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

There is insufficient data on the use of CALBICOR® in pregnant women. CALBICOR® should not be used during pregnancy unless absolutely necessary.

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

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

It is unknown whether CALBICOR® is excreted in human milk. The decision to discontinue breastfeeding or CALBICOR® therapy should be made considering the benefits of breastfeeding for the child and the benefits of CALBICOR® therapy for the woman.

Driving and using machines

While using CALBICOR®, you may experience dizziness. This is more likely to occur when starting treatment, when your treatment is changed, or when consuming alcohol. If you experience dizziness, do not drive or operate any tools or machines. If you encounter any issues that might affect your ability to drive or operate machinery while taking CALBICOR®, consult your doctor.

Important information about the excipients in CALBICOR®

CALBICOR® contains lactose monohydrate derived from cows. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Interaction with other medicines

Inform your doctor or pharmacist if you are currently using, have recently used, or may use any other medicine.

- Diuretics (water pills), other heart and blood pressure medications including calcium channel blockers (e.g., diltiazem or verapamil)
- Monoamine oxidase inhibitors (MAOIs) such as isocarboxazid and phenelzine (used to treat depression)
- Diabetes medications like insulin and metformin
- Clonidine (used to treat high blood pressure, migraine, and menopausal hot flashes)
- Rifampicin (used to treat infections)
- Cimetidine (used to treat indigestion, heartburn, and stomach ulcers)
- Cyclosporine (used post-organ transplant)
- Fluoxetine (used to treat depression)
- Non-steroidal anti-inflammatory drugs (NSAIDs) like aspirin, indomethacin, and ibuprofen
- Beta blockers (used to treat chest tightness, wheezing from asthma, or other chest-related conditions like salbutamol and terbutaline sulfate)

If you are currently taking or have recently taken any prescription or non-prescription medication, please inform your doctor or pharmacist.

3. How to use CALBICOR®?**• Instructions for appropriate use and dosage/application frequency:**

Always use CALBICOR® exactly as your doctor has told you. If you are not sure, consult your doctor or pharmacist.

Chronic Heart Failure:

When used for heart failure, treatment with CALBICOR® should be initiated by a specialist doctor.

You should take the tablets with food.

The usual starting dose is 3.125 mg twice a day for two weeks.

Your doctor will then gradually increase the dose in weekly intervals up to 25 mg twice a day. If you weigh more than 85 kg (187 lbs), the dose can be increased up to 50 mg twice a day.

If you have stopped taking CALBICOR® for more than two weeks, you should speak to your doctor. You will need to return to the starting dose.

High Blood Pressure:

The usual starting dose is 12.5 mg once a day for two days. After two days, the dose is usually 25 mg once a day.

If your blood pressure is not controlled, your doctor may gradually increase the dose weekly up to 50 mg.

If you are elderly, you may not need more than 12.5 mg once a day to control your blood pressure.

Angina:

The starting dose is 12.5 mg twice a day for two days.

After two days, the dose is 25 mg twice a day.

• Method and route of administration:

Swallow each tablet with a glass of liquid.

• Different Age Groups

Use in Children:

CALBICOR® is not suitable for use in children under 18 years of age.

Use in the Elderly:

Your doctor will decide on your starting dose and the best dose for long-term use. The normal maximum dose is 50 mg once a day, taken in divided doses.

• Special Usage Cases:

Kidney Failure:

Based on available data on patients with varying degrees of kidney failure, no dosage adjustment of carvedilol is recommended for patients with moderate to severe kidney failure.

Liver Failure:

Carvedilol should not be used in patients with clinically significant liver failure. Your doctor will determine the dose of your medication based on your illness and administer it to you.

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

If you take more CALBICOR® than you should:

If you have taken more CALBICOR® than you should or if someone else has taken your CALBICOR® tablets, consult your doctor or go to the hospital immediately. Take the medication package with you.

Taking too many tablets can cause the following effects:

- Slow heart rate
- Dizziness and a feeling of lightheadedness
- Shortness of breath
- Extreme fatigue

If you have taken more CALBICOR® than you should, talk to a doctor or pharmacist.

If you forget to take CALBICOR®:

If you forget to take a dose, take it as soon as you remember. However, if it is close to the time for your next dose, skip the missed dose.

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

Effects when CALBICOR® treatment is stopped

Do not stop taking this medicine without talking to your doctor. Your doctor will advise you to gradually reduce the dose of CALBICOR® over 1 to 2 weeks rather than stopping suddenly. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Potential side effects

Like all medications, CALBICOR® may cause side effects in individuals who are sensitive to its ingredients.

Stop using CALBICOR® and IMMEDIATELY inform your doctor or go to the nearest emergency department of the hospital if you experience any of the following:

- Difficulty breathing, swelling of the face, lips, tongue, or throat, sudden drop in blood pressure, widespread and severe redness, itching, hives (urticaria).

These are all very serious side effects.

If you experience any of these, you may have a serious allergy to CALBICOR®.

May require urgent medical intervention or hospitalization.

These very serious side effects are rare.

Side effects are categorized as follows:

Very common	: Can occur in at least 1 out of 10 patients.
Common	: Can occur in less than 1 out of 10, but more than 1 out of 100 patients.
Uncommon	: Can occur in less than 1 out of 100, but more than 1 out of 1000 patients.
Rare	: Can occur in less than 1 out of 1000, but more than 1 out of 10000 patients.
Very rare	: Can occur in less than 1 out of 10000 patients.
Not known	: Frequency cannot be estimated from the available data.

Very common:

- Feeling dizzy
- Headache (usually mild and occurs at the beginning of treatment)
- Feeling weak and tired
- Heart-related disorders. Symptoms include chest pain, fatigue, shortness of breath, and swelling in the arms and legs.
- Low blood pressure. Symptoms include dizziness and lightheadedness, especially when standing up.

Common:

- Inflammation of the bronchi, lungs, inflammation of the nose and throat (respiratory tract inflammation). Symptoms include wheezing and/or shortness of breath, chest tightness, and throat pain.
- Inflammation in the urinary system (may cause problems in urination).
- Decrease in red blood cells (anemia). Symptoms include feeling tired, pale skin color, palpitations, and difficulty breathing.
- Weight gain
- Increase in cholesterol levels (shown by blood test)
- Impaired blood sugar control in people with diabetes
- Feeling depressed
- Slowing of heart rate and dizziness or lightheadedness when standing up (these effects are usually seen at the beginning of treatment)
- Fluid retention. Symptoms include swelling in hands, feet, and legs, and increased blood volume in the body.
- Disorders related to circulation in arms and legs. Symptoms include cold hands and feet, whitening of the skin, tingling and pain in the fingers, and worsening leg pain when walking.
- Breathing problems
- Feeling unwell and sick.
- Diarrhea
- Vision problems
- Dryness in the eyes due to decreased tear production
- Dizziness, tiredness, and headache (these effects are usually mild and occur at the beginning of treatment)
- Stomach ache. Symptoms include feeling unwell, stomach pain, and diarrhea.
- Pain in hands and feet

- Kidney problems (including changes in frequency of urination)

Uncommon:

- Fainting
- Sleep disorders
- Numbness or tingling in the hands or feet
- Constipation
- Increased sweating
- Skin-related issues, including widespread skin rashes, bumpy rashes (urticaria), itching sensation, and dry, flaking skin.
- Difficulty in achieving erection (erectile dysfunction)
- Hair loss

Rare:

- Low platelet count in your blood. Symptoms include easy bruising of the skin and nosebleeds.
- Nasal congestion, shortness of breath, symptoms similar to a common cold
- Dry mouth

Very rare:

- Low white blood cell count. Symptoms may include mouth, gum, throat, and lung infections.
- Kidney problems indicated by blood tests.
- Some women may have difficulty maintaining bladder control (urinary incontinence). This condition usually improves when treatment is discontinued.
- Acute severe allergic reactions. Symptoms include sudden swelling of the throat or face, difficulty breathing and swallowing, swelling of hands, feet, and ankles.
- Serious skin reactions such as Stevens-Johnson syndrome (skin peeling, swelling, blisters, and fever) and toxic epidermal necrolysis (severe skin reactions with fluid-filled blisters and tissue loss).

CALBICOR® can also cause symptoms of diabetes in individuals with a mild form of diabetes known as "latent diabetes."

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storage of CALBICOR®

Store CALBICOR® in a place where children cannot see or reach it, and keep it in its original packaging.

Store below 30°C.

Use CALBICOR® in accordance with the expiration date.

Do not use CALBICOR® after the expiration date printed on the packaging.

Do not use CALBICOR® if you notice any defects in the product or packaging.

Do not dispose of expired or unused medication in the trash! Dispose of them according to the collection system established by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:

Santa Farma Ilac Sanayii A.S.

Halide Edip Adivar Mahallesi, Boru Cicegi Sokak No 16

Sisli, Istanbul, Turkey

Tel: (+90 212) 220 64 00

Fax: (+90 212) 222 57 59

Manufacturer:

Demirciler Osb Mahallesi, Erol Kiresepi Caddesi No 8 Gebze V Kimya Ihtisas Organize Sanayi

Bolgesi, Dilovasi, 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]