

**PATIENT INFORMATION LEAFLET**  
**EFNOCAR Tablets 10 mg / 20 mg / 40 mg**  
**Efonidipine Hydrochloride Ethanolate**

The name of your medicine is EFNOCAR 10 mg / 20 mg / 40 mg Tablets. We refer to them as EFNOCAR Tablets or EFNOCAR throughout this leaflet.

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 more questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to anyone else. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects that are not listed in the leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What EFNOCAR Tablets are and what they are used for
2. What you need to know before you take EFNOCAR Tablets
3. How to take EFNOCAR Tablets
4. Possible side effects
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6. Contents of the pack and other information

## **1. WHAT EFNOCAR TABLETS ARE AND WHAT THEY ARE USED FOR**

EFNOCAR Tablets contain the active substance efonidipine which belongs to a group of medicines called calcium antagonists.

EFNOCAR Tablets may be used to treat:

- High blood pressure (hypertension)
- hypertension caused by kidney disease
- A certain type of chest pain called angina

In patients with high blood pressure, these medicines work by relaxing blood vessels, so that blood passes through them more easily. In patients with angina, EFNOCAR works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. EFNOCAR Tablets do not immediately relieve chest pain caused by angina.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EFNOCAR TABLETS**

### **Do not take EFNOCAR Tablets if you:**

- Have ever had an allergic reaction to efonidipine or any of the ingredients in the tablet. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- If you are pregnant

### **Take special care with EFNOCAR Tablets**

You should inform your doctor if you have or have had any of the following conditions:

- Liver disease;
- Recent heart attack;
- Heart failure;
- Severe increase in blood pressure (Hypertensive crisis).

### **Use in children and adolescents**

EFNOCAR is not recommended in infants and children as safety is not established in this group of patients.

For more information, talk to your doctor.

### **Taking other medicines and EFNOCAR**

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription.

EFNOCAR may affect or be affected by other medicines, such as:

- Other antihypertensive agent/s (BP lowering drugs)
- Cimetidine (stomach acid reducer)
- Tacrolimus (a drug to suppress immunity)

EFNOCAR may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

If you see another doctor or go into hospital for any reason, tell them that you are taking EFNOCAR Tablets.

### **Taking EFNOCAR Tablets with food and drink**

You should not drink grapefruit juice or eat grapefruit while taking this medicine. Grapefruit and grapefruit juice can lead to an increase in the blood levels of efonidipine, which can cause an unpredictable increase in its blood pressure lowering effect.

### **Pregnancy**

The safety of efonidipine in human pregnancy has not been established. Efonidipine should not be administered in pregnant women.

### **Breast-feeding**

It is not known whether efonidipine is passed into breast milk. Efonidipine should not be administered in breast-feeding women.

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

### **Driving and using machines**

Dizziness may occur while taking antihypertensive agents. Hence, working on aerial platform, working with dangerous machinery and/or driving should be avoided.

## **3. HOW TO TAKE EFNOCAR TABLETS**

Swallow these tablets with a glass of water at the same time each day. You can take the tablets after meals.

Follow your doctor's instructions. Check the pharmacy label to see how many tablets to take and how often to take them. If you are still not sure, ask your pharmacist or doctor. The usual doses are described below.

### **Adults**

Essential hypertension and renal parenchymal hypertension: 20-40 mg orally once daily. A dose of up to 80 mg/day has been reported to be safe and effective in clinical trials.

Angina: 40 mg/day.

### **Children**

EFNOCAR is not recommended in infants and children as safety is not established in this group of patients.

### **Elderly**

EFNOCAR should be started with a low dose (20mg/day). Your doctor will closely monitor your response to any decrease in the dose.

### **Patients with liver disease**

Your doctor may give you a different dose to normal.

### **If you take more EFNOCAR Tablets than you should**

If you (or someone else) swallow a lot of tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Take your medication and the packaging with you to the doctor or casualty department. If you have taken an overdose, you may appear flushed (your skin will look red), or you may feel dizzy or faint. If blood pressure drop is severe enough shock can occur.

### **If you forget to take EFNOCAR Tablets**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining doses at the correct time.

#### **If you stop taking EFNOCAR Tablets**

Take this medicine for as long as your doctor tells you to, as you may become unwell if you stop.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The common side effects are hot flushes, palpitations, facial flushing and headache. In addition, elevation in serum total cholesterol, ALT (SGPT), AST (SGOT) and BUN may occur.

Other known side effects are as follows. Tell your doctor if you notice or are worried by any of the side effects listed.

##### **Frequency 0.1 to < 5%**

- Increased AST (SGOT), ALT (SGPT), LDH, Alkaline Phosphatase
- BUN rise, serum creatinine rise, proteinuria
- Decreased hemoglobin, decreased hematocrit, decreased red blood cells
- Rash, itching
- Palpitations, chest pain, decreased blood pressure
- Flushing of the face
- Headache, sluggishness and light-headedness
- Nausea, stomach discomfort, abdominal pain
- Malaise, serum total cholesterol rise, CK (CPK) increased, uric acid increased, hypokalemia

##### **Frequency Less than 0.1%**

- Increase in bilirubin
- Eosinophilia, leukopenia, thrombocytopenia
- Bradycardia, tachycardia, atrial fibrillation, premature ventricular contraction
- Hot flushes, sweating
- Drowsiness, numbness, and tinnitus
- Vomiting, constipation
- Frequent urination, edema, increased triglycerides

##### **Frequency unknown**

- Sick sinus syndrome, atrioventricular junctional rhythm, atrioventricular block, shock
- Diarrhea, Gingival hyperplasia

Tell your doctor or pharmacist if you notice any other effects not listed.

## **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: [www.zuventus.co.in](http://www.zuventus.co.in) and click the tab “Safety Reporting” located on the top right end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

## **5. HOW TO STORE EFNOCAR TABLETS**

Do not use the tablets after the end of the expiry month (use-by date) shown on the product packaging.

Store below 25°C. Protected from light & moisture.

## **KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What EFNOCAR Tablets contain**

- The active substance is Efonidipine Hydrochloride Ethanolate.

Each tablet contains 10 mg / 20 mg / 40 mg of Efonidipine.

- Other ingredients: Excipients q.s.

### **Marketing authorisation holder:**

Zuventus Healthcare Ltd.

A Joint venture of Emcure, India

### **Manufacturer responsible for batch release:**

Zuventus Healthcare Ltd.

A Joint venture of Emcure,

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