

# BETAC

Betaxolol Hydrochloride (20mg)

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## What BETAC is used for

BETAC is used to treat high blood pressure (hypertension) or a certain type of chest pain called Angina pectoris.

## How BETAC works

BETAC is one of a group of medicines called cardioselective beta-adrenoceptor blocking agents.

It works by affecting the response to nerve impulses in certain parts of the body, to relax the blood vessels and slow down the heart beat and thus decreases the blood pressure. When the blood pressure is lowered, the amount of blood and oxygen is increased to the heart, to avoid heart pain.

## Before you use BETAC

### When you must not use it

Do not use BETAC if:

- you are **allergic** to betaxolol or any of the other ingredients of this medicine (listed in **Product Description**)
- you have a **heart or blood vessel disease (other than the one you are taking BETAC for)**
- you are taking some medicines called floctafenine or sultopride

### Before you start to use it

Before you take BETAC you should tell your doctor if:

- you have asthma or other conditions affecting the respiratory tract
- you have **diabetes and you are taking insulin**
- you have **liver** or **renal** disease
- you have **thyroidal** problems where the thyroid glands, produce either too much or too little thyroid hormones
- you have **glaucoma**, a condition of increased pressure in the eyeball causing gradual loss of sight

- you have **psoriasis**, a skin disease causing the skin to be itchy and red

If any of the above applies to you, talk to your doctor who will decide what to do.

In the case of surgery, you should inform the anaesthetist that you take BETAC.

### Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

It is especially important to tell the doctor if you are taking:

- Other medicines to reduce blood pressure
- Medicines to lower blood sugar
- Medicine to treat heart conditions such as vasodilators

## How to use BETAC

### How much to use

Unless otherwise prescribed by your doctor, the recommended adult dose is 20mg daily.

### Renal impairment

It is advisable to adjust the dosage according to the state of the renal function; for a creatinine clearance over 20 ml per minute, it is not necessary to change the dosage. However, clinical monitoring is recommended at the start of the treatment until the equilibration of blood levels is reached (4 days on average).

In case of severe renal insufficiency (creatinine clearance < 20ml/min), the initial recommended dose is 10mg/day (taken irrespective of the frequency and timing of dialysis sessions for dialysed patients.)

### Hepatic impairment

In the case of **hepatic impairment** the usual adult dose is 20mg daily.

**BETAC is not recommended for children and adolescents (<18 years)**

### When to use it

Always take BETAC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### How long to use it

It is very important that you keep taking the medicine as long as the doctor recommended. Do not stop if you feel better.

### If you forget to use it

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for a missed dose.

### If you use too much (overdose)

If you have accidentally taken more than your prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

Taking too many tablets may cause dizziness, faintness and low blood pressure.

## While you are using it

### Things you must do

Take your medicine exactly as your doctor has advised you.

Tell the doctor, pharmacist or dentist treating you that you are taking BETAC.

Tell your doctor immediately if you become pregnant while taking this medication.

### Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give BETAC to anyone else, even if they have the same symptoms or condition as you.

### Things to be careful of

#### *Pregnancy, breast-feeding and fertility*

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### *Driving and using machines*

This medicine may affect your ability to drive or operate machines.

**BETAC contains lactose monohydrate.** If you have been told by your doctor that you are lactose

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intolerant, contact your doctor before taking this medicine.

## Side effects

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

Those most frequently reported are:

- asthenia (weakness)
- cool extremities
- bradycardia (slow heart rate), possibly severe
- digestive disorders (abdominal pain, nausea, vomiting)
- impotence
- insomnia

Much more infrequent:

- slowing of the atrioventricular or worsening of a pre-existing atrioventricular block, a disease in the electrical system of the heart, which will affect the rate and rhythm of heartbeats.
- cardiac insufficiency (a situation where the heart cannot pump enough blood throughout the body)
- a drop in blood pressure
- bronchospasm (where the muscles around the airways in the lungs go into spasm)
- hypoglycaemia (low blood sugar)
- Raynaud's syndrome
- aggravation of pre-existing intermittent claudication (muscle pain caused by lack of blood flow during exercise)
- various skin manifestation including psoriasis-like (characterised by red, scaly patches of skin) rashes or flare up of psoriasis
- paresthesia (pins and needles)
- eye dryness
- nightmares

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)**

## Storage and Disposal of BETAC

### Storage

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

Store below 25°C in the original package to protect the tablets from light and moisture.

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

### Disposal

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 to protect the environment.

## Product Description

### What it looks like

BETAC 20mg film-coated tablets are white, round, convex and scored.

BETAC 20mg film-coated tablets are available in blister packs. Box sizes of 30, 50 and 100 tablets are available.

Not all pack sizes may be marketed.

### Ingredients

- *Active ingredient* is betaxolol (as hydrochloride). Each tablet contains betaxolol hydrochloride 20mg.
- *Inactive ingredients* are lactose monohydrate, cellulose microcrystalline, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, titanium oxide (E171), polyvinyl alcohol, talc, lecithin, xanthan gum.

### MAL No.

MAL06081203A

### **Manufacturer**

MEDOCHEMIE LTD, 1-10  
Constantinoupoles street, 3011  
Limassol, Cyprus

### **Product Registration Holder**

KOMEDIC SDN BHD, 4 Jalan PJS  
11/14, Bandar Sunway, 46150  
Petaling Jaya

### **Date of Revision**

20/03/2014