Betaxolol hydrochloride belongs to a group of medicines called beta-blockers. These medicines lower blood pressure, slow heart rate and reduce the heart oxygen consumption.

Betaxolol hydrochloride is used for the treatment of high blood pressure (hypertension) in adults, of mild to moderate forms.

It is also used for long-term treatment of attacks of stable angina pectoris (chest pain resulting from insufficient blood supply to the heart muscle due to exertion or stress) in adults.

Do not take Betaxolol hydrochloride if you:

- are allergic to betaxolol or any of the other ingredients of this medicine (listed in section 6)
- have severe asthma and another serious breathing problem called chronic obstructive lung disease (COPD), which makes you breathless when active with a cough with phlegm and suffer from frequent chest infections
- have severe heart failure
- have cardiogenic shock (failure of the heart to pump effectively)
- have heart conduction disturbances which prevent your heart from beating normally (second and third degree atrioventricular block, unless you have a pacemaker)
- have Prinzmetal's variant angina pectoris (chest pain while resting)
- have sick-sinus syndrome, including sinoatrial block (missed heart beats)
- have significantly slow heart rate
- have a severe form of Raynaud's syndrome and peripheral arterial disorder (causing poor circulation in arms and legs)
- have untreated adrenal gland tumour (pheochromocytoma)
- have low blood pressure
- have a history of severe allergic reactions which cause difficulty breathing with swelling of the nose, lips and eyelids (anaphylactic reaction)
- have higher than normal levels of acid in your blood (metabolic acidosis)
- are taking floctafenine (a medicine used for mild to moderate pain relief) or sultopride (a medicine used to treat schizophrenia)

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Betaxolol hydrochloride if you:

- have less severe forms of chronic obstructive lung disease and asthma. Examination of your lung function is recommended before the start of treatment
- have kidney problems
- have heart failure and are also being treated with medicines to help this condition,
- have other heart conduction disturbances (first degree atrioventricular block)
- have less severe forms of Raynaud's Syndrome, inflammation of the blood vessels walls or blockage (reducing blood flow) of the blood vessels
- are receiving treatment for a tumour of the adrenal glands called pheochromocytoma, which causes high blood pressure. Treatment of high blood pressure (hypertension) requires special measures, and your doctor will regularly test your blood pressure
- have diabetes and are prone to hypoglycemia (low blood sugar). This medicine may mask warning signs of low blood sugar such as fast uneven heartbeat and sweating. Patients with diabetes should monitor their blood sugar at more frequent intervals, especially at the start of treatment
- have glaucoma (increased pressure in the eye). Before any eye examination, tell your eye doctor or optician that you are taking this medicine
- have a family or personal history of psoriasis
- have thyrotoxicosis (a condition caused by an overactive thyroid gland). This medicine may hide symptoms

**During treatment**

Talk to your doctor or pharmacist before you receive treatment for an allergy (known as desensitisation therapy), because betaxolol may increase your risk of having an allergic reaction and may also reduce the effectiveness of some medicines used to treat allergic reactions.

When taking this medicine, if you notice a large reduction in heart rate (less than 50-55 beats per minute), talk to your doctor.

If you are fasting/dieting, or are exercising heavily this medicine may increase the risk of developing low blood sugar. This medicine may also mask warning signs of low blood sugar. If you are concerned, talk to your doctor or pharmacist.

If you are due to have medical scans or X-rays, where you are to be injected with a dye beforehand, tell your doctor or hospital staff that you are taking this medicine. Your doctor may need to stop this medicine.
If you are to be given general anesthesia during surgery, tell the anesthetist or hospital staff that you are taking this medicine.

**Children and adolescents**
Do not give this medicine to children and adolescents as safety and efficacy have not been established.

**Other medicines and Betaxolol Hydrochloride**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The product **must not** be taken if you are taking floctafenine, a medicine used to reduce pain and swelling or sultopride, a medicine used in the treatment of schizophrenia.

Betaxolol hydrochloride is **not recommended** for use with the following:
- amiodarone and digoxin (medicines to treat heart rhythm problems)
- fingolimod, (a medicine used for treating multiple sclerosis)
- verapamil (used in the treatment of high blood pressure (hypertension) and heart problems)
- some medicines used to treat depression (known as MAOI-As, e.g. moclobemide)

Your doctor may carry out regular tests and checks in order to make sure that your medicine is working and that your heart is not affected by the combination of the medicines, if you are taking any of the following:
- calcium channel blockers (medicines used to treat high blood pressure (hypertension), e.g. bepridil, diltiazem, mibebradil)
- medicines used in heart rhythm disorders e.g. propafenone, quinidine, hydroquinidine, disopyramide
- baclofen (a drug reducing muscle tension)
- lidocaine (a local anaesthetic)
- iodine-containing contrast media (a dye which may be injected into the body before some medical scans e.g. MR scans, CT scans and X-rays to improve the pictures of inside the body)
- anti-diabetes medication e.g. insulin, glimepiride, as you may not notice that your blood sugar is low (hypoglycaemia) because this medicine may mask warning signs such as fast uneven heartbeat and sweating. You will need to measure your blood sugar levels more often especially at the start of treatment
- some general anaesthetics used in surgery; you should tell your anaesthetist or hospital staff that you are taking this medicine
- cimetidine (for stomach problems)
- hydralazine (used for high blood pressure (hypertension))

If you take any of the following medicines, talk to your doctor, because taking these medicines may affect the way that this medicine works.
- medicines used in the treatment of pain and inflammation, known as non-steroidal anti-inflammatory drugs (NSAIDS)
- medicines that help relax the blood vessels (also known as calcium channel blockers) used for high blood pressure or some circulation problems, e.g. nifedipine, amlodipine
- some medicines used to treat depression and mental health conditions e.g. imipramine
- corticosteroids and tetracosactides (a type of hormonal treatment)
- mefloquine (a medicine to treat malaria)
- sympathomimetics (medicines that may increase heart rate, e.g. phenylephrine)
If you have been taking a medicine called clonidine at the same time as this medicine, and you need to stop taking clonidine, your doctor may stop you taking betaxolol for a few days before you stop treatment with clonidine.

**Betaxolol hydrochloride with alcohol**
You should not drink alcohol while taking this medicine.

**Pregnancy and breast-feeding**
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.

There is a risk that betaxolol treatment during pregnancy may harm the baby. Tell your doctor if you are pregnant or planning to become pregnant. Your doctor will decide whether you can take betaxolol during pregnancy.

Betaxolol is present in breast milk, therefore its use is not recommended during breast-feeding.

**Driving and using machines**
Due to its possible side effects (fatigue, dizziness), especially at the start of treatment, the product may adversely affect activities requiring alertness, coordination and quick decision-making (e.g. driving, operating machinery, working at heights, etc.). In such case you should perform these activities only with the approval of your doctor.

**Betaxolol hydrochloride contains lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. **How to take Betaxolol hydrochloride**
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adults**
Your doctor will decide how much Betaxolol you should take.

In mild hypertension the recommended initial dose is 10 mg (1/2 tablet) once daily usually in the morning. In case of insufficient effect, this dose can be increased to 20 mg (1 tablet) per day.

In moderate hypertension the recommended dose is 20 mg once daily, however the doctor may increase the dosage to 40 mg (2 tablets) per day.

The recommended daily dose in stable angina pectoris is one tablet. Your doctor may adjust the dosage from 10 to 40 mg (1/2 to 2 tablets) per day.

**Patients with kidney problems**
If you have mild kidney problems, your doctor may give you the recommended dose. If you have more severe kidney problems, your doctor may lower your dose. If you are on dialysis, the recommended dose is 10 mg (1/2 tablet) per day, regardless of the timing of dialysis.

**Patients with liver problems**
If you have liver problems, your doctor will give you the recommended dose, but may carry out tests to make sure that your liver is working properly especially at the start of the treatment.

**Elderly patients**

Your doctor may start you on a lower dose.

The tablet can be divided into equal doses.

**If you take more Betaxolol hydrochloride than you should**

In case of overdose or accidental ingestion of the product by a child it is necessary to seek medical help immediately. You may feel faint, dizzy, feel your heart beating more slowly, with chest pain, breathing problems and occasionally fits.

**If you forget to take Betaxolol hydrochloride**

In case of a missed morning dose you can take the medicine during the day and continue the prescribed dosage regimen the next day. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Betaxolol hydrochloride**

Always contact your doctor or pharmacist before you stop taking this medicine. Treatment with betaxolol hydrochloride should not be stopped abruptly. If treatment withdrawal is necessary, your doctor may reduce the dosage gradually.

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

4. **Possible side effects**

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

**If you notice the following, contact your doctor or go to the nearest hospital casualty department straight away.**

- You have chest pain, feel your heart beating very slowly, feel faint, are short of breath and dizzy, especially if you have been told by your doctor that you have a problem with the rate or rhythm of your heartbeat; this may be due to problems with the way your heart beats (slowed atrioventricular conduction or aggravation of pre-existing atrioventricular block)
- Feeling breathless, tired with swollen ankles (heart failure)
- Swelling of the joints, feeling exhausted with rash over the cheeks and nose (systemic lupus erythematosus, a disease where the immune system attacks parts of the body, which may be confirmed by blood tests)

**Other possible side effects**

**Common (may affect up to 1 in 10 people):**

- fatigue, dizziness, headache, sweating
- weakness, trouble sleeping (insomnia)
- stomach pain, diarrhoea, feeling sick (nausea) and vomiting
- slow heart beat (bradycardia)
- feeling cold in extremities
- problems with getting and maintaining an erection (impotence)
- allergic skin reactions (redness, itching, rash) and hair loss
Rare (may affect up to 1 in 1,000 people):
- skin disease with thickened patches of red skin, often with silvery scales (psoriasis), worsening of the symptoms of an existing psoriasis or psoriasiform eruptions
- depression
- feeling dizzy, light headed, faint, unsteady with a feeling of loss of balance (low blood pressure)
- discoloration of fingers (Raynaud’s syndrome), worsening of pain due to impaired blood circulation in the lower limbs
- breathing difficulties such as wheezing which may be due to narrowing of the airways

Very rare (may affect up to 1 in 10,000 people):
- visual problems
- seeing, feeling or hearing things that are not there (hallucinations), confusion, nightmares
- tingling of the hands and feet (distal parathesia)
- feeling hungry, dizzy, tired, confused, with trembling, sweating, blurred vision and pale skin, which may be due to low blood sugar (hypoglycaemia)
- feeling tired and thirsty with a dry mouth and needing to pass water more often, especially at night, which may be due to high blood sugar (hyperglycaemia)

Not known (cannot be estimated from the available data):
- fatigue
- urticaria (hives)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via het Nederlands Bijwerkingen Centrum Lareb, website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Betaxolol hydrochloride**

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

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

This medicine does not require any special storage conditions

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 protect the environment.

6. **Contents of the pack and other information**

**What Betaxolol hydrochloride contains**

The active substance is betaxolol hydrochloride. Each tablet contains 20 mg betaxolol hydrochloride.

The other ingredients are:
Core
Microcrystalline cellulose [E460], lactose monohydrate (see section 2, “Betaxolol contains lactose”),
sodium starch glycolate, silica, colloidal anhydrous [E551], magnesium stearate [E470b]

Film-coating
Hypromellose [E464], titanium dioxide [E171], macrogol 400 [E1521].

What Betaxolol Hydrochloride looks like and contents of the pack

Betaxolol hydrochloride 20 mg are white, round, biconvex film-coated tablets with a break-line on one face.

Betaxolol hydrochloride is available in blisters of 28, 30 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen

Mylan B.V.
Dieselweg 25
3752 LB Bunschoten
Nederland

Fabrikant

Delpharm Reims
10 Rue Colonel Charbonneaux
51100 Reims
Frankrijk

In het register ingeschreven onder het volgende nummer: RVG 116165

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Tsjechië  Betaxolol Mylan 20 mg, potahované tablety
Polen  Betaxomyl
Slovakije  Betaxolol Mylan 20 mg, filmom obalené tablety
Nederland  Betaxolol HCl Mylan 20 mg, filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in januari 2018.