

CONSUMER MEDICINE INFORMATION

HYBLOC

Labetalol hydrochloride 50mg, 100mg, 200mg and 400mg Tablets

What is in this leaflet

This leaflet answers some common questions about HYBLOC. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking HYBLOC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet. You may want to read it again.

What HYBLOC is used for and how it works

Your HYBLOC tablets contain the active ingredient labetalol hydrochloride. It belongs to a group of medicines known as beta blockers. It works by changing the body's response to some nerve impulses. As a result, it widens blood vessels in the body causing blood pressure to fall.

HYBLOC is used to lower high blood pressure, also called hypertension. HYBLOC is also useful in the treatment of angina (chest pain) in patients who also suffer from high blood pressure.

Your doctor may, however, prescribe HYBLOC for another reason. **Ask your doctor if you have any questions about why HYBLOC has been prescribed for you.**

There is no evidence that HYBLOC is addictive.

HYBLOC is available on prescription from your doctor.

Before you take HYBLOC

When you must not take it

Do not take HYBLOC if:

- You are allergic to labetalol hydrochloride or any other ingredients listed at the end of this leaflet
- You have certain other heart problems, including uncontrolled heart failure
- You have a very slow heart beat, less than 45-50 beats per minute
- You have asthma, wheezing, difficulty breathing or other lung problems
- You have low blood pressure
- You have an untreated tumour of the adrenal gland (phaeochromocytoma)
- You have a disturbance of the body's acid-base balance
- You have blood circulatory problems

Symptoms of an allergic reaction may include:

- shortness of breath,
- wheezing or difficulty breathing,
- swelling of the face, lips, tongue or other parts of the body,
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take HYBLOC

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Any liver problems such as jaundice
- A heart condition or a history of heart problems
- You are pregnant or plan to become pregnant
- You are breastfeeding or plan to breastfeed
- You have psoriasis (a skin disease)

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and HYBLOC may interfere with each other. These include:

- Tricyclic antidepressants, a group of medicines used to treat depression
- Monoamine oxidase inhibitors, medicines used in the treatment of depression
- Phenothiazines, a group of medicines used to treat severe mental conditions
- Barbiturates, a group of medicines used to treat epilepsy and other conditions
- Cimetidine, a medicine commonly used to treat stomach ulcers
- Certain medicines used to treat an irregular heartbeat (e.g. disopyramide, quinidine, amiodarone).
- Calcium channel blockers, medicines used to treat high blood pressure and angina (e.g. verapamil, diltiazem, bepridil, nifedipine)
- Some medicines used during surgery and emergency situations such as anaesthetics
- Other blood pressure medication (e.g. clonidine, methyldopa).
- Fluid tablets, also called diuretics
- Insulin and other antidiabetic medicines
- Anti-inflammatory medicines
- Sympathomimetic agents (e.g. adrenaline)
- Digoxin, a medicine used to treat heart conditions.

These medicines may be affected by HYBLOC or may affect how well HYBLOC works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking HYBLOC.

How to take HYBLOC

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much HYBLOC you need to take each day. It is important that you take HYBLOC as directed by your doctor. Do not take more than the recommended dose.

The usual starting dose of HYBLOC for adults is one 100mg tablet twice daily.

In patients already receiving antihypertensives, the elderly, those people of low body weight and for patients with newly diagnosed mild hypertension (high blood pressure), a dose of one 50mg tablet twice daily may be more appropriate.

The use of HYBLOC is not recommended for children.

How to take it

Tablets should be taken with food. The first dose is best taken in the evening at bedtime.

How long to take it

HYBLOC helps to control your condition but does not cure it. Therefore HYBLOC must be taken everyday. Continue taking HYBLOC for as long as your doctor prescribes.

If you forget a dose

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking HYBLOC

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking HYBLOC.

Tell any other doctors, dentists or pharmacists who treat you that you are taking HYBLOC.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking HYBLOC.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking HYBLOC. It may affect other medicines used during surgery.

If you are going to have any blood tests, tell your doctor that you are taking HYBLOC. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take HYBLOC to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking HYBLOC or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as chest pain, irregular heart beat and high blood pressure. If possible your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how HYBLOC affects you. HYBLOC may cause dizziness, light-headedness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking HYBLOC. Alcohol can affect the way in which HYBLOC works.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking HYBLOC.

This medicine helps most people with high blood pressure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Dizziness or light-headedness, especially when getting up quickly
- Headache
- Tiredness, lack of energy
- Depressed mood
- Tingling of the skin, especially the scalp
- Problems with sexual function
- Nausea, vomiting or stomach upset
- Blocked nose, sweating, swollen ankles

The above list includes the more common side effects of HYBLOC. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- Any type of skin rash, itching or hives
- Chest tightness, wheezing, shortness of breath
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Fast, slow or irregular heart beat
- Feeling generally unwell, sometimes with yellowing of the eyes or skin (jaundice)
- Difficulty in passing urine
- Muscle and joint pain, which may occur together with fever and skin rash
- Hallucinations or confusion
- Cold extremities.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation. These side effects are usually rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any HYBLOC by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of HYBLOC with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the label or if the packaging shows signs of tampering.

Keep your HYBLOC tablets in the container until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store HYBLOC or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking HYBLOC or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What HYBLOC tablets look like

HYBLOC 50 mg Tablets: Orange film coated biconvex tablet, 7/32" (5.6 mm) diameter, imprinted 'LB' on one side and blank on the other side.

HYBLOC 100 mg Tablets: Orange film coated biconvex tablet 9/32" diameter, imprinted 'LB' over '100' on one side and blank on the other side

HYBLOC 200 mg Tablets: Orange film coated biconvex tablet 3/8" diameter, imprinted 'LB' over '200' on one side and blank on the other side.

HYBLOC 400mg Tablets: Orange film coated biconvex tablet 1/2" (12.7 mm) diameter, imprinted 'LB over 400' on one side

Each HYBLOC tablet contains the active ingredient, labetalol hydrochloride.

Each HYBLOC tablet also contains lactose, maize starch, pregelatinised maize starch, sodium starch glycollate, magnesium stearate and the film coat (diethyl phthalate, hypromellose and opaspray orange). All tablets are polished with carnauba wax.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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