

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## HYBLOC

### *Labetalol hydrochloride film-coated Tablets*

*50 mg, 100 mg and 200 mg*



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## What is in this leaflet

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Please read this leaflet carefully before you start taking HYBLOC.

This leaflet answers some common questions about HYBLOC.

It does not contain all the available information. 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 with the medicine.** You may need to read it again.

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## What HYBLOC is used for

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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 treat

- High blood pressure (hypertension)
- Chest pain (angina pectoris) 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.

There is not enough information to recommend the use of HYBLOC for children.

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## Before you take HYBLOC

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### *When you must not take it*

**Do not take HYBLOC if you have an allergy to:**

- any medicine containing labetalol hydrochloride.
- any of the ingredients listed at the end of this leaflet.
- Some of the 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 HYBLOC if:**

- 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.

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breast-feed if you are taking this medicine.**

The active ingredient in HYBLOC passes into breast milk (if applicable) and there is a possibility that your baby may be affected.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start [using/taking] this medicine, talk to your doctor.**

### *Before you start to take it*

**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 plan to become pregnant
- You plan to breastfeed
- You have psoriasis (a skin disease).
- History of cataracts (blurred vision or difficulty seeing).

**If you have not told your doctor about any of the above, tell them before you start taking HYBLOC.**

## ***Taking other medicines***

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

You should also tell any health professional who is prescribing a new medication for you that you are taking HYBLOC.

Some medicines may interfere with HYBLOC. These include:

- Tricyclic antidepressants, a group of medicines used to treat depression
- Monoamine oxidase inhibitors, medicines used to treat 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, hydralazine, methyldopa, ACE inhibitors, angiotensin-II antagonists)
- 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
- Medicines used to treat malaria, such as mefloquine or quinine
- Moxisylyte and alprostadil, medicines used to treat erectile dysfunction
- Medicines containing the hormones oestrogen or progesterone
- Sleeping pills
- Medicines used to treat anxiety
- Aldesleukin, a medicine used to treat certain types of cancer
- Ergot derivatives, a group of medicines used to treat migraine headaches.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take HYBLOC**

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**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 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.

**Swallow the tablets whole with a full glass of water.**

### ***When to take it***

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep [using/taking] your medicine even if you feel well.

### ***If you forget to take it***

**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.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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## **While you are taking HYBLOC**

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### ***Things you must do***

**If you are about to be started on any new medicine, tell your**

**doctor and pharmacist that you are taking HYBLOC.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are [using/taking] this medicine.**

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

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** 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 your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine 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.**

This medicine may cause dizziness, light-headedness, tiredness and drowsiness 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 this medicine.**

Alcohol can affect the way in which HYBLOC works.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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## **In case of overdose**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much HYBLOC. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

Symptoms of an overdose may include a slow heart beat, low blood pressure, shortness of breath or wheezing.

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## **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.**

**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
- Sleep disturbances
- Tingling of the skin, especially the scalp
- Problems with sexual function
- Nausea, vomiting or stomach upset
- Dry eyes, impaired vision
- Blocked or runny nose
- Sweating
- Swollen ankles.

The above list includes the more common side effects of your medicine.

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

- Any type of skin rash, itching or hives
- Worsening of psoriasis (patches of red skin with white silvery scales)
- Feeling generally unwell, sometimes with yellowing of the eyes or skin (jaundice)
- Difficulty in passing urine
- Muscle and joint weakness or pain, which may occur together with fever and skin rash
- Hallucinations or confusion
- Cold extremities
- Fast, slow or irregular heart beat
- Wheezing or coughing.

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- Chest tightness, wheezing, shortness of breath
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**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. Tell your doctor if you notice any other effects.

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

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## After taking HYBLOC

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### Storage

**Keep your tablets in the bottle until it is time to take them.**

If you take the tablets out of the bottle 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### What it looks 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.

### Ingredients

#### Active ingredient(s):

HYBLOC contains 50, 100 or 200 mg of Labetalol hydrochloride as the active ingredient.

#### Inactive ingredient(s):

HYBLOC also contains:

- Lactose
- Maize starch
- Pregelatinised maize starch
- Sodium starch glycollate
- Magnesium stearate

The film coat contains:

- diethyl phthalate
- hypromellose
- hypolose
- sunset yellow
- titanium dioxide

All tablets are polished with carnauba wax.

This medicine does not contain gluten.

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## If you want to know more

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

### Who supplies this medicine

HYBLOC is supplied in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Eilerslie,  
Auckland  
NEW ZEALAND

Telephone: (09) 579 2792

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## Date of Preparation

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01 July 2019

(Based on datasheet dated 01 July 2019)