

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I receiving LETYBO?

LETYBO contains the active ingredient LetibotulinumtoxinA. It is used to temporarily improve glabellar frown lines in adults, which are the vertical frown lines between your eyebrows.

For more information, see Section [1. Why am I receiving LETYBO?](#) in the full CMI.

### 2. What should I know before I am given LETYBO?

Do not receive this medicine if you have ever had an allergic reaction to LETYBO or any of the ingredients listed at the end of the CMI, if you have muscle activity disorders or if you have an infection or inflammation at the proposed injection sites.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given LETYBO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with LETYBO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given LETYBO?

LETYBO therapy can only be initiated by a doctor with experience in handling this medicine. Your doctor will determine the dose you need.

Further details can be found in Section [4. How will I be given LETYBO?](#) in the full CMI.

### 5. What should I know while receiving LETYBO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are being treated with LETYBO.</li><li>• Keep your appointments with your doctor and check for any side effects.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how LETYBO affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• LETYBO is administered by your doctor.</li></ul>

For more information, see Section [5. What should I know while receiving LETYBO?](#) in the full CMI.

### 6. Are there any side effects?

The common side effects observed may include headache, head discomfort, migraine, common cold symptoms, droopy eyelids, dizziness, impaired vision and injection site pain and bruising. The serious side effects may include difficulty in swallowing, breathing and speaking.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# LETYBO®

**Active ingredients:** LetibotulinumtoxinA

## Consumer Medicine Information (CMI)

This leaflet provides important information about LETYBO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about LETYBO.**

**Where to find information in this leaflet:**

- [1. Why am I receiving LETYBO?](#)
- [2. What should I know before I am given LETYBO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given LETYBO?](#)
- [5. What should I know while receiving LETYBO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I receiving LETYBO?

**LETYBO contains the active ingredient letibotulinumtoxinA.**

This medicine belongs to a family of medicines called peripheral muscle relaxants.

**LETYBO is used to temporarily improve the look of frown lines between the eyebrows (glabellar lines) in adults.**

LETYBO is injected into the muscles. It works by blocking nerve impulses to the muscles in which it has been injected. It prevents muscles from contracting, leading to a temporary paralysis of the muscle it has been injected into.

### 2. What should I know before I am given LETYBO?

#### Warnings

This product contains a small amount of albumin. The risk of transmission of viral infection or prion-related infection such as Creutzfeldt-Jakob Disease (CJD) cannot be excluded with absolute certainty following the use of human blood or blood products.

The healthcare professionals will record the name and batch number(s) of LETYBO used in order to maintain a record of the batch used and trace any possible infection source.

**Do not receive LETYBO if:**

- you are allergic to letibotulinumtoxinA or any of the ingredients listed at the end of this leaflet
- if you have muscle activity disorders, such as myasthenia gravis, Lambert-Eaton syndrome, amyotrophic lateral sclerosis

- if you have acute infection or inflammation at the proposed injection sites.

**Check with your doctor if you:**

- have or ever have had any other medical conditions including the following:
  - any disorder affecting muscles and/or their direct nervous system control
  - difficulties swallowing or breathing, or have had these in the past
  - a bleeding disorder.

In some cases, the effect of the botulinum toxin may affect areas of the body away from the injection side. This can very rarely cause side effects such as excessive muscle weakness and could result in swallowing and breathing difficulties. These side effects are serious and can result in death.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

LETYBO is not recommended if you are pregnant or breastfeeding.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### 3. What if I am taking other medicines?

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

**Some medicines can interfere with the way LETYBO works. These include:**

- muscle relaxants
- some antibiotics

These medicines may increase the risk of having side effects after receiving LETYBO.

### 4. How will I be given LETYBO?

Your doctor will prepare and administer this medicine. Your doctor will have received training and be experienced in giving LETYBO.

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

### How much to receive?

Your doctor will determine the correct dosage to give you.

### When will you be given LETYBO?

Your doctor will tell you how often you will require treatment with this medicine.

LETYBO will be given to you according to a treatment schedule. There may be some weeks apart between treatments.

### If you are given too much LETYBO

Your doctor will know how much LETYBO to give you. As it is given to you by your doctor, it is very unlikely that you will receive an overdose.

However, if you believe that you have been given too much LETYBO:

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while receiving LETYBO?

### Things you should do:

- Keep your appointments with your doctor and check for any side effects.

### Call your doctor straight away if you:

- become or intend to become pregnant.
- are breastfeeding or intend to breastfeed.

Remind any doctor, dentist, or pharmacist you visit that you are being treated with LETYBO.

### Things you should not do:

**Be careful before you drive or use any machines or tools until you know how LETYBO affects you.**

LETYBO may cause weakness, muscle weakness, vision disorders, drooping eyelids or dizziness in some people.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• headache, head discomfort, migraine</li><li>• common cold symptoms</li><li>• droopy eyelids</li><li>• eyelid twitching</li><li>• dizziness</li><li>• impaired vision</li><li>• injection site pain and bruising</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Potential serious side effects	What to do
<ul style="list-style-type: none"><li>• difficulty in swallowing</li><li>• difficulty in breathing</li><li>• difficulty in speaking</li></ul>	<b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking or receiving any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What LETYBO contains:

<b>Active ingredients (main ingredients)</b>	LetibotulinumtoxinA
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Albumin</li><li>• Sodium chloride</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What LETYBO looks like**

LETYBO (letibotulinumtoxinA) 50 U Powder for injection (AUST R 370012) is a white freeze-dried powder supplied in clear glass vials closed with rubber stoppers and sealed with aluminium seals.

LETYBO (letibotulinumtoxinA) 100 U Powder for injection (AUST R 370011) is a white freeze-dried powder supplied in clear glass vials closed with rubber stoppers and sealed with aluminium seals.

LETYBO is available in vials containing 50 or 100 units.

Each pack contains one vial.

## **Who distributes LETYBO?**

Sponsor:

Croma Australia Pty Ltd

Level 26, 1 Bligh Street

Sydney NSW 2000

Australia

This leaflet was prepared in November 2022