

## 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.

### 1. Why am I using COMBIGAN®?

COMBIGAN® eye drops contains the active ingredient brimonidine tartrate and timolol maleate. COMBIGAN® is used to lower raised pressure in the eye(s) and to treat glaucoma.

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

### 2. What should I know before I use COMBIGAN®?

Check the list of ingredients at the end of the CMI. Do not use COMBIGAN® if you have ever had an allergic reaction to any of them.

**Talk to your doctor before you use this medicine if he/she is not aware that 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 use COMBIGAN®?](#) in the full CMI.

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

Some medicines may interfere with COMBIGAN® and affect how it works, or COMBIGAN® may interfere with other medicines and affect how they work.

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

### 4. How do I use COMBIGAN®?

Your doctor will tell you how many drops you need to use each day. The usual dosage of eye drops is one drop in the eye(s) two times a day. More instructions can be found in Section [4. How do I use COMBIGAN®?](#) in the full CMI.

### 5. What should I know while using COMBIGAN®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using COMBIGAN®</li><li>Continue to use COMBIGAN® every day unless your doctor tells you to stop</li><li>Keep all your appointments so your condition can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not touch the dropper tip against your eye, eye lid or any surface</li><li>Do not stop using COMBIGAN® without checking with your doctor.</li><li>Do not use COMBIGAN® while you are wearing soft contact lenses.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Wait for your vision to clear after using COMBIGAN® before you drive or use machines.</li><li>Do not drive or operate machines if you feel tired or drowsy while using COMBIGAN®.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>COMBIGAN® may cause drowsiness and this can be made worse by drinking alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Follow all instructions on the carton and bottle label.</li><li>Store below 25°C, away from moisture, heat, or sunlight.</li></ul>

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

### 6. Are there any side effects?

The most common side effect is redness of the eye or eyelids or a burning or stinging sensation in the eye. You may also experience blurry vision and tearing. Serious side effects include, severe allergic reaction, including swelling of the tongue, lips and throat, difficulty breathing, heart failure, fast or irregular heart beat and high blood pressure.

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.

# COMBIGAN® (com-bi-gan)

Active ingredient(s): brimonidine tartrate (brim-on-id-deen tar-trate) and timolol maleate (Tl-moh-lol mā-lē-ātē)

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using COMBIGAN®?](#)
- [2. What should I know before I use COMBIGAN®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use COMBIGAN®?](#)
- [5. What should I know while using COMBIGAN®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using COMBIGAN®?

COMBIGAN® contains the active ingredient brimonidine tartrate and timolol maleate.

COMBIGAN® is used to lower raised pressure in the eye and to treat glaucoma.

Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure.

Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight.

Eye damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist.

If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

COMBIGAN® eye drops lower the pressure in the eye by decreasing the fluid produced and helping the flow of fluid out of the eye chamber.

Although COMBIGAN® eye drops help control your glaucoma, it does not cure it.

COMBIGAN® belongs to a family of medicines called alpha-adrenergic agonists.

Your doctor may have prescribed COMBIGAN eye drops for another reason. Ask your doctor if you have any

questions about why COMBIGAN® eye drops have been prescribed for you.

### 2. What should I know before I use COMBIGAN®?

#### Warnings

**Do not use COMBIGAN® if:**

- You are allergic to brimonidine tartrate, timolol maleate or any of the ingredients listed at the end of this leaflet.
- You are taking monoamine oxidase antidepressant medication
- you have bronchospasm, bronchial asthma or have a history of bronchial asthma or other lung disease
- you have a severe or unstable or uncontrolled heart condition
- Do not use in children younger than 2 years of age.
- The seal around the cap is broken
- The bottle/packaging shows signs of tampering
- The product does not look quite right
- The expiry date on the bottle or carton has passed. If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using COMBIGAN® eye drops, talk to your doctor.

#### Check with your doctor if you:

Have had an allergy to any other medicine or any other medicines or any other foods, preservatives, or dyes.

Have or have had any medical conditions, especially the following:

- liver or kidney disease
- severe, uncontrolled heart disease or poor blood flow to the heart
- poor blood flow to the brain
- depression
- lung disease including asthma
- you have diabetes mellitus or an overactive thyroid
- you have low blood pressure
- you have a disease called myasthenia gravis which can cause muscle weakness or other symptoms common to that disease
- you are due to have surgery under general anaesthetic
- Raynaud's syndrome. This is a condition marked by numbness, tingling and colour change (white, blue, then red) in the fingers when they are exposed to cold
- Dizziness on standing up, especially when getting up from a sitting or lying position

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

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks and benefits of using COMBIGAN® when pregnant or breastfeeding.

## Use in children

Do not use COMBIGAN® eye drops in a child or adolescent. Safety and effectiveness in paediatric patients have not been established. It is particularly important that the medicine is not used in children under the age of 2 years.

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

Tell your doctor or pharmacist 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 may interfere with COMBIGAN® and affect how it works, while COMBIGAN® may affect how other medicines work.**

**Do not take COMBIGAN® if you are taking any of the following medicines:**

- medicines for high blood pressure
- certain medicines to treat depression, such as monoamine oxidase inhibitors and tricyclics
- sedative-type medicines, alcohol and antihistamines
- sympathomimetic medicines
- antidiabetic agents
- some drugs prescribed for heart problems/conditions (e.g. isoprenaline, digitalis glycosides, anti-arrhythmics and quinidine)
- any drugs used to increase the size of blood vessels (e.g. guanethidine)
- Medicines used to treat asthma, severe headaches or coughs and colds may belong in the sympathomimetic group.

These medicines may be affected by COMBIGAN® eye drops 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 or pharmacist has more information on medicines to be careful with or avoid while using COMBIGAN® eye drops.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COMBIGAN®.**

## 4. How do I use COMBIGAN®?

### How much to use

- Your doctor will tell you how many drops you need to use each day.
- The usual dosage of eye drops is one drop in the eye(s) two times a day (approximately every 12 hours).

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

### When to use COMBIGAN®

- Use COMBIGAN eye drops every day, at about the same time each day, unless your doctor tells you otherwise. Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

In some instances, COMBIGAN® needs to be used with other eye drops. Your doctor will let you know which drops, how to use them, and how long to use them.

Wait at least 5 to 10 minutes after using COMBIGAN® before using other eye drops.

### How to use COMBIGAN®

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

To open a new bottle of COMBIGAN eye drops, first tear off the protective seal from the bottle. The contents are sterile if seal is intact. The seal will break, and you can pull it off and then throw it away.

1. Wash your hands well with soap and water.
2. Shake the bottle gently.
3. Remove the cap.
4. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your lower eyelid. Do not let the tip touch your eye or eyelid.
8. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
9. Close your eye. Do not blink or rub your eye or eyelid.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
11. Replace the cap, sealing it tightly.
12. Wash your hands again with soap and water to remove any residue.
13. If you wear contact lenses, wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

Contaminated eye drops may give you an eye infection.

COMBIGAN® eye drops are for use in eyes only.

**You may feel a slight burning sensation in the eye shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.**

#### If you forget to use COMBIGAN®

It is important that you use COMBIGAN® at the same time each day.

**If you forget to use COMBIGAN® and it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.**

**Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.**

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

#### If you use too much COMBIGAN®

Immediately rinse your eyes with warm water.

#### If COMBIGAN® is accidentally swallowed:

- 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 appear to be no signs of discomfort or poisoning.**

## 5. What should I know while using COMBIGAN®?

#### Things you should do

- Continue to use COMBIGAN® as instructed by your doctor. COMBIGAN® helps to control your condition but does not cure it.
- Use all the medication prescribed to treat your eye condition.
- Keep all your doctor's appointments so that your condition can be monitored, and your eye pressure can be checked.
- If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor. Your doctor may tell you to use a new container of COMBIGAN® eye drops because of possible contamination of the old one or may advise you to stop your treatment with COMBIGAN® eye drops.

#### Call your doctor straight away if you:

- suspect an eye infection (e.g. redness, discharge, pain)
- become pregnant while using COMBIGAN®.

Remind any doctor, dentist or pharmacist or optometrist you visit that you are using COMBIGAN®.

#### Things you should not do

- Do not touch the dropper tip against your eye, eyelid or anything else, to avoid contaminating the eye drops.
- Do not stop using COMBIGAN® without checking with your doctor. Your eye pressure can rise again and may cause damage to your eye.

#### Driving or using machines

- Wait for your vision to clear after using COMBIGAN® before you drive or use machines.
- Do not drive or operate machines if you feel fatigued or drowsy while using COMBIGAN®.

#### Drinking alcohol

COMBIGAN® may cause drowsiness and this can be made worse by drinking alcohol.

#### Looking after your medicine

Store below 25°C.

To avoid contamination of the solution, keep container tightly closed. Do not touch the dropper tip to any surface. Contents are sterile if seal is intact.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

**Keep it where young children cannot reach it.**

#### When to discard your medicine

##### Discard the bottle 4 weeks after first opening it.

Write the date on the bottle when you open the eye drops and throw out the remaining solution after four weeks. Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

#### Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not open the bottle to use this medicine after the expiry date has passed.

## 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
<b>Effects on the eye(s)</b> <ul style="list-style-type: none"> <li>Red congested eyes</li> <li>Burning or stinging sensation in the eye</li> <li>Conjunctivitis (discharge with itching of the eye and crusty eyelids)</li> <li>Inflammation of the undersurface of the eyelids</li> <li>Distorted vision</li> <li>Nodules on the undersurface of the eyelid</li> <li>Overflow of tears down the cheek</li> <li>Eye dryness, pain/ache, irritation, tiredness or itchiness</li> <li>Red, swollen or itchy eyelids</li> <li>Discharge from the eye</li> <li>Feeling of something in the eye(s)</li> <li>Decrease in sharpness of vision</li> <li>Swelling of the white part of the eye or the front part of the eyeball</li> <li>Small images floating through or across your vision</li> <li>Excessive sensitivity to bright light</li> <li>Eyelid pain</li> <li>Whitening of the conjunctiva</li> <li>Detachment of the gel like substance from the back of the eye</li> <li>Abnormalities of the front surface of the eye</li> <li>Blurred vision</li> </ul> <b>Effects on the body as a whole:</b> <ul style="list-style-type: none"> <li>Tiredness and weakness</li> <li>Sleepiness/drowsiness</li> <li>Headache</li> <li>Dizziness</li> <li>Fainting</li> <li>Depression</li> <li>Skin rash</li> <li>Runny nose</li> <li>Nasal dryness</li> <li>Dryness of mouth</li> <li>Abnormal taste</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>
	<p><b>Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.</b></p> <p>Other side effects not listed here may occur in some people.</p> <p><b>Reporting side effects</b></p> <p>After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="http://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.</p> <p><b>Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.</b></p>

## Serious side effects

What to do
<ul style="list-style-type: none"> <li>Fast or irregular heart beat</li> <li>High blood pressure</li> </ul>

**these serious side effects.**

**Tell your doctor or pharmacist 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 any of your medicines.**

## 7. Product details

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

### What COMBIGAN® contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>Brimonidine tartrate</li> <li>Timolol maleate</li> </ul>
<b>Preservative</b>	<ul style="list-style-type: none"> <li>benzalkonium chloride</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>dibasic sodium phosphate heptahydrate</li> <li>monobasic sodium phosphate monohydrate</li> <li>purified water</li> <li>sodium hydroxide</li> <li>hydrochloric acid</li> </ul>

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

### What COMBIGAN® looks like

COMBIGAN® is a clear, greenish-yellow solution. It is supplied in a plastic dropper bottle containing 5 mL of liquid.

(AUST R 97690).

### Who distributes COMBIGAN®

COMBIGAN® is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

Australia

Toll-free: 1800 252 224

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## Serious side effects

Serious side effects	What to do
<b>Body as a whole:</b> <ul style="list-style-type: none"> <li>Severe allergic reaction, including swelling of the tongue, lips and throat, difficulty breathing</li> <li>Heart failure</li> </ul>	<b>Go straight to the Emergency Department at your nearest hospital if you notice any of</b>

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