

COMBIGAN™ EYE DROPS

Consumer Medication Information Leaflet (RiMUP)

brimonidine tartrate/timolol (2mg/5mg per 1ml)

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What **COMBIGAN™** is used for

COMBIGAN™ is prescribed to reduce high pressure in the eye of people with glaucoma or high pressure in the eye when other medicines like beta-blocker eye drops used alone are not enough.

How **COMBIGAN™** works

COMBIGAN™ works by reducing the production of liquid in the eye and increasing the amount of liquid that is drained away. This reduces the eye pressure.

Before you use **COMBIGAN™**

- When you must not use it

Do not use **COMBIGAN™**:

- If you are allergic (hypersensitive to brimonidine tartrate, timolol, beta-blockers, or any of the other ingredients of **COMBIGAN™**. (for a full list of ingredients, see section "PRODUCT DESCRIPTION"). Symptoms of an allergic reaction may include swelling of the face, lips and throat, wheeziness, feeling faint, shortness of breath, itching or redness around the eye.
- if you have now or have had in the past breathing problems such as asthma or severe chronic obstructive lung disease.
- if you have heart problems such as low heart rate, heart failure, heart

beat disorders (unless controlled by a pacemaker).

- if you are taking monoamine oxidase (MAO) inhibitors or certain other antidepressant medicines.

If you think any of these points apply to you, do not use **COMBIGAN™** until you have talked again to your doctor.

- Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant or planning to become pregnant.

Do not use **COMBIGAN™** if you are pregnant unless your doctor considers it necessary.

Do not use **COMBIGAN™** if you are breast-feeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

- Children

COMBIGAN™ should not be used in children less than 2 years old. Safety and effectiveness of **COMBIGAN™** in children and adolescents (2 to 17 years of age) have not established and therefore, its use is not recommended in children or adolescents.

- Before you start use it

Take special care with **COMBIGAN™**.

Before you take this medicine, tell your doctor:

- if you have now or have had in the past:
 - coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
 - poor blood circulation disease (such as Raynaud's phenomenon)

- diabetes, as timolol may mask signs and symptoms of low blood sugar levels
- over activity of the thyroid gland, as timolol may mask signs and symptoms
- kidney or liver problems
- tumour of the adrenal gland
- eye surgery to lower the pressure in your eye
- any allergy (e.g. hayfever, eczema) or a severe allergic reaction be aware that the usual dose of adrenaline used to control a severe reaction may need to be increased.
- if your body produces excessive quantities of acid or when the kidneys are not removing enough acid from the body.

Tell the doctor before you have an operation that you are using **COMBIGAN™**, as the timolol may change effects of some medicines during anaesthesia.

- Taking other medicines

COMBIGAN™ can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

There are a number of medicines which may interfere with **COMBIGAN™**, so it is particularly important to tell your doctor if you are taking:

- barbiturates, opiates or anaesthetics
- medicines to help you sleep or for anxiety or depression (for example sedatives, selective serotonin reuptake inhibitors, tricyclic antidepressants or MAO inhibitors)
- medicines to treat high blood pressure (for example prazosin or hydralazine)
- medicines used to treat heart conditions and some types of malaria e.g. beta-blockers, digoxin, anti-arrhythmics, calcium channel blockers or quinidine
- medicines to treat diabetes
- another eye drop used to lower high pressure in the eye (glaucoma)

- medicines that affect some of the hormones in your body, like adrenaline
- medicines to treat heartburn or stomach ulcers (for example: Cimetidine)

If the dose of any of your current medicines is changed or if you are regularly consuming alcohol you should tell your doctor. If you are due to have an anaesthetic, you should tell the doctor or dentist that you are taking **COMBIGAN™**.

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

How to use COMBIGAN™

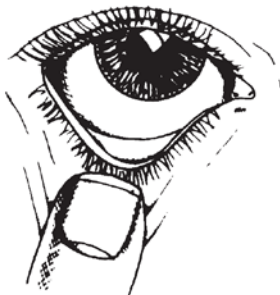
How much to use

The usual dose is one drop of **COMBIGAN™**, twice a day about 12 hours apart. Do not change the dose or stop taking it without speaking to your doctor. If you have other eye drops as well as **COMBIGAN™**, leave at least 5 minutes between using **COMBIGAN™** and the other eye drops.

Instructions for use:

Wash your hands before opening the bottle. Tilt your head back and look at the ceiling.

1. Gently pull down the lower eyelid until there is a small pocket.



2. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment.



3. Let go of the lower lid, and close your eye.



4. Keep the eye closed and press your finger against the corner of your eye (the side where your eye meets your nose) for one minute. This helps stop **COMBIGAN™** get into the rest of the body.



If a drop misses your eye, try again. To avoid contamination or eye injury, do not let the tip of the bottle touch your eye or anything else. Put the screw-cap back on to close the bottle, straight after you have used it.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking **COMBIGAN™** for as long as your doctor recommends.

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

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Babies and Children:

Several cases of overdose have been reported in babies and children less than 2 years of age receiving brimonidine (one of the ingredients of **COMBIGAN™**) as part of medical treatment for glaucoma. Signs include sleepiness, loss of consciousness, low blood pressure, floppiness, slow heartbeat, low body temperature, bluish discoloration of the skin due to inadequate oxygenation of the blood, temporary cessation of breathing especially during sleep, tiredness, paleness and breathing difficulties. Should this happen, contact your doctor immediately.

Adults and Children:

Slow heartbeat has been reported with the use of higher than recommended dose. Timolol overdose may cause dizziness, headache, shortness of breath, slow heartbeat, low blood pressure, difficulty in breathing and heart suddenly stops pumping blood.

If **COMBIGAN™** has been accidentally swallowed then you should contact your doctor immediately.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking **COMBIGAN™**.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give **COMBIGAN™** to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines:

COMBIGAN™ has minor influence on the ability to drive and use machines. **COMBIGAN™** may cause transient blurring of vision, fatigue and/or drowsiness which may impair the ability to drive or operate machines. You should wait until these symptoms have cleared before driving or using machinery.

Using contact lenses:

COMBIGAN™ contains benzalkonium chloride as a preservative, which is known to discolour soft contact lenses and can cause eye irritation. If you wear soft contact lenses you must remove them before using **COMBIGAN™** eye drops and wait at least 15 minutes before putting your lenses back in.

Side effects

Like all medicines, **COMBIGAN™** can cause side effects, although not everybody gets them.

The chance of having a side effect is described by the following categories:

- **Very common:** Occurs in more than 1 out of 10 people
- **Common:** Occurs in fewer than 1 out of 10 people but more than 1 out of 100 people

The following side effects may be seen with **COMBIGAN™**.

Affecting the eyes:

Very Common: red eye, burning sensation

Common:

- stinging sensation in the eye
- itchy eyes
- watery eyes
- eye dryness
- eye pain
- eye discharge
- eye irritation
- foreign body sensation
- eye allergy
- visual disturbance
- red itchy eyelids
- eyelid swelling

Affecting other parts of the body:

Common: depression, drowsiness, headache, high blood pressure, mouth dryness, physical weakness, abnormal liver function test

Additional side effects have been seen with brimonidine or timolol and therefore may potentially occur with **COMBIGAN™**.

Brimonidine:

- inflammation inside the eye
- constricted pupil
- difficulty in sleeping
- irregular heartbeat
- upper respiratory symptoms
- shortness of breath
- gastrointestinal symptoms
- systemic allergic reactions

A high incidence of feeling drowsy or sleepy has been reported in children 2 years of age and above, especially those in the 2-7 age range and/or weighing < 20 Kg.

Timolol:

- decreased eye sensitivity, double vision, drooping of the eyelid, choroid layer detachment (following eye surgery), eye power changes.
- difficulty in sleeping, nightmares, decreased sex drive, memory loss, anxiety, confusion, disorientation, hear, smell, taste or feel things that do not exist, nervousness, increase in signs and symptoms of chronic disease leading to muscle

- weakness and fatigue, prickling skin, oxygen shortage in the brain
- ringing in ear
- heart block, irregular heartbeat, heart failure, chest pain, water retention in the lungs
- difficult breathing, cough, reduction in lung function
- indigestion, abdominal pain
- hair loss, scaly skin
- autoimmune disease where the body's immune system mistakenly attacks healthy tissues in many parts of the body
- formation of scar tissue in the penis

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of COMBIGAN™

- Storage

Keep out of the reach and sight of children. On prescription only. Keep the bottle in the outer carton.

Do not use **COMBIGAN™** after the expiry date which is stated on the bottle label and the bottom of the carton after EXP.

Store below 30°C.

- Disposal

Discard unused contents 4 weeks after opening.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

COMBIGAN™ is a clear, greenish-yellow to light greenish-yellow eye drops are supplied sterile in white opaque plastic dropper bottles of 5 mL.

- Ingredients

- Active ingredients
brimonidine tartrate and timolol

- Inactive ingredients
Benzalkonium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, hydrochloric acid or sodium hydroxide to adjust pH, and purified water

- MAL number:

MAL20081812AZ

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

Product Registration Holder

Allergan Malaysia Sdn Bhd
Level 5-02, Block A, PJ8, No.23, Jalan Barat, Seksyen 8, 46050 Petaling Jaya, Selangor, Malaysia

Date of revision

05/07/2018

Serial Number:

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