

COMBIGAN® EYE DROPS

(brimonidine tartrate 2.0 mg per mL and timolol (as maleate) 5.0 mg per mL)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about COMBIGAN® eye drops. 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 using COMBIGAN® eye drops against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What COMBIGAN[®] eye drops are used for

COMBIGAN[®] eye drops are 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. 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 condition, it does not cure it.

COMBIGAN® eye drops are only available with a doctor's prescription from pharmacies. 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.

Before you use COMBIGAN® eye drops

When you must not use it

Do not use COMBIGAN® eye drops if:

- you have an allergy to brimonidine tartrate, timolol or any of the ingredients listed at the end of this leaflet, some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or

tongue, which may cause difficulty in swallowing or breathing

- 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
- 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 has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in COMBIGAN® eye drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used COMBIGAN® eye drops.

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.

These drops are for topical use only.

Before you start to use it

Tell your doctor if:

1. you have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.

2. you have severe or unstable or uncontrolled heart disease or a history of severe heart disease.
3. you have a disease affecting your blood vessels, including Raynaud's phenomenon.
4. you have depression.
5. you have a lung disease including asthma.
6. you have liver or kidney disease.
7. you have diabetes mellitus or an overactive thyroid.
8. you have low blood pressure.
9. you have a disease called myasthenia gravis which can cause muscle weakness or other symptoms common to that disease.
10. you are pregnant or intend to become pregnant. Like most medicines COMBIGAN® eye drops should not be used during pregnancy, unless the benefits outweigh the risk to the baby.
11. you are breast-feeding or intend to breast-feed. Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.
12. you are due to have surgery under general anaesthetic.

Taking other medicines

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

Some medicines and COMBIGAN[®] eye drops may interfere with each other. These include:

- 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.

How to use COMBIGAN[®] eye drops

How much to use

Your doctor will tell you how many drops you need to use each day. Use COMBIGAN[®] eye drops only as prescribed by your doctor.

The usual dose of COMBIGAN[®] eye drops is one drop in the affected eye(s) twice daily, approximately 12 hours apart.

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

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.

If you are using more than one eye drop product, wait 5 to 10 minutes before using the second product.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

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 the 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. Remove the lid/cap.
3. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
4. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
5. Tilt your head back and look up.
6. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
7. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
8. Close your eye. Do not blink or rub your eye.
9. 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.

10. Replace the lid/cap, sealing it tightly.
11. Wash your hands again with soap and water to remove any residue.

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.

How long to use it

COMBIGAN[®] eye drops help control your condition, but do not cure it. Therefore, COMBIGAN[®] eye drops must be used every day. Continue using COMBIGAN[®] eye drops for as long as your doctor prescribes.

If you forget to use it

If 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.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of COMBIGAN® eye drops, immediately telephone your doctor or Poisons Information Centre (Australia : telephone 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using COMBIGAN[®] eye drops

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure COMBIGAN[®] eye drops are working.

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.

If you become pregnant while using COMBIGAN[®] eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using COMBIGAN[®] eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using COMBIGAN[®] eye drops.

If you are about to start any new medicine tell your doctor and pharmacist that you are using COMBIGAN[®] eye drops.

Things you must not do

Do not give COMBIGAN[®] eye drops to anyone else, even if they have the same condition as you.

Do not stop using COMBIGAN[®] eye drops without first talking to your doctor. If you stop using your eye drops, your eye pressure may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how COMBIGAN[®] eye drops affect you. COMBIGAN[®] eye drops generally should not cause any problems with your ability to drive or operate machinery. However, COMBIGAN[®] eye drops may cause blurred vision/ dizziness/ drowsiness/ tiredness in some people. Make sure you know how you react

to COMBIGAN® eye drops or that your vision is clear before driving or operating machinery.

Side effects

Tell your optical practitioner, doctor or pharmacist as soon as possible if you do not feel well while you are using COMBIGAN® eye drops.

COMBIGAN® eye drops help most people with high eye pressure and glaucoma, 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 this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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

- Red, congested eyes
- Burning or stinging sensation in the eye
- Conjunctivitis (discharge with itching of the eye and crusty eyelids)
- Inflammation of the undersurface of the eyelids
- Visual disturbance or abnormal vision
- Nodules on the undersurface of the eyelid
- Overflow of tears down the cheek
- Eye dryness, pain/ache, irritation, tiredness or itchiness
- Red, swollen or itchy eyelids
- Discharge from the eye
- Feeling of something in the eye(s)
- Decrease in sharpness of vision
- Swelling of the white part of the eye or the front part of the eyeball
- Small images floating through or across your vision
- Excessive sensitivity to bright light
- Eyelid pain

- Whitening of the conjunctiva
- Detachment of the gel like substance from the back of the eye
- Abnormalities of the front surface of the eye.

Other side effects that may be experienced are as follows:

Tiredness and weakness, sleepiness/drowsiness, headache, dizziness, fainting, depression,

heart failure, fast or irregular heart beat, high blood pressure, skin rash, runny nose, nasal dryness, abnormal liver function tests, oral dryness and abnormal taste.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using COMBIGAN[®] eye drops

Storage

Keep your COMBIGAN[®] eye drops in a cool place where the temperature stays below 25°C.

Keep the bottle where children cannot reach it.

Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Throw out any remaining solution after four weeks from the date of opening.

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.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What COMBIGAN[®] eye drops look like:

Clear, greenish-yellow sterile solution.

Ingredients

Active ingredient:

Brimonidine tartrate 2.0 mg/mL and timolol (as maleate) 5.0 mg/mL

Preservative:

Benzalkonium chloride

Inactive ingredients:

Dibasic sodium phosphate heptahydrate

Monobasic sodium phosphate monohydrate

Hydrochloric acid

Sodium hydroxide

Purified water

Manufacturer/Supplier

AbbVie Pty Ltd

241 O’Riordan Street

Mascot NSW 2020

Australia

Toll free: 1800 252 224 (Australia)

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

New Zealand Freephone: 0800 659 912 (NZ)

COMBIGAN[®] eye drops can be identified by registration number: AUST R 97690

For more information about glaucoma, contact Glaucoma Australia on 1800 500 880 or Glaucoma New Zealand on

09 373 8779

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