PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

COMBIGAN 2 mg/ml + 5 mg/ml eye drops, solution

Brimonidine tartrate and timolol

Read all of this leaflet carefully before you start using COMBIGAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COMBIGAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What COMBIGAN is and what it is used for
2. What you need to know before you use COMBIGAN
3. How to use COMBIGAN
4. Possible side effects
5. How to store COMBIGAN
6. Contents of the pack and other information

1. What COMBIGAN is and what it is used for

COMBIGAN is an eye drop that is used to control glaucoma and high pressure in the eye. It contains two different medicines (brimonidine and timolol) that both reduce high pressure in

the eye.

2. What you need to know before you use COMBIGAN

Do not use COMBIGAN

- If you are hypersensitive (allergic) to brimonidine tartrate, timolol, beta-blockers or any of the other ingredients of COMBIGAN (listed in section 6). 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 ever have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough) or bronchospasm (constricting of the air passageways causing breathing difficulties);
- If you have heart problems such as low heart rate, heart failure, heartbeat disorders (unless controlled by a pacemaker);
- If you are taking monoamine oxidase (MAO) inhibitors or within 2 weeks of stopping MAO-inhibitor therapy, or if you are taking linezolid or certain other antidepressant medicines;
- COMBIGAN should not be used in children less than 18 years old.

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

Warnings and precautions

- Before using COMBIGAN, 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 or low blood pressure;
  - Disturbances of the heart rate such as slow or irregular heart beat;
  - Breathing problems, asthma or chronic obstructive pulmonary disease;

- Poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome);
- Diabetes as timolol may mask signs and symptoms of low blood sugar levels;
- Overactivity 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.

- If you suffer or have suffered from any allergy (e.g. hay fever, eczema) or have had a severe allergic reaction be aware that the usual dose of adrenaline used to control a severe reaction may need to be increased;
- Tell the doctor before you have an operation that you are using COMBIGAN, as the timolol may change effects of some medicines given during anaesthesia.

Children

COMBIGAN should not be used in children less than 18 years old.

Other medicines and COMBIGAN

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

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

- pain killers;
- medicines to help you sleep or for anxiety;
- medicines to treat high blood pressure (hypertension);

- medicines for heart conditions (for example an abnormal heartbeat) such as beta-blockers, digoxin or quinidine (used to treat heart conditions and some types of malaria);
- medicines to treat diabetes or high blood sugar;
- medicines for depression such as fluoxetine and paroxetine;
- another eye drop used to lower high pressure in the eye (glaucoma);
- medicines to treat severe allergic reactions;
- medicines that affect some of the hormones in your body, like adrenaline and dopamine;
- medicines that affect the muscles in your blood vessels;
- medicines to treat heartburn or stomach ulcers.

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 using COMBIGAN.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care for advice before using COMBIGAN.

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

Do not use COMBIGAN if you are breastfeeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breastfeeding.

Driving and using machines

COMBIGAN may cause drowsiness, tiredness or blurred vision. Do not drive or use any tools or machines until the symptoms have cleared. If you experience any problems, talk to your doctor.

COMBIGAN contains benzalkonium chloride

Contact lenses:

- A preservative in COMBIGAN (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.
- Do not use COMBIGAN while your contact lenses are in your eyes. Wait at least 15 minutes after using COMBIGAN before putting your lenses back in.

3. How to use COMBIGAN

Do not share medicines prescribed for you with any other person.

Always use COMBIGAN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

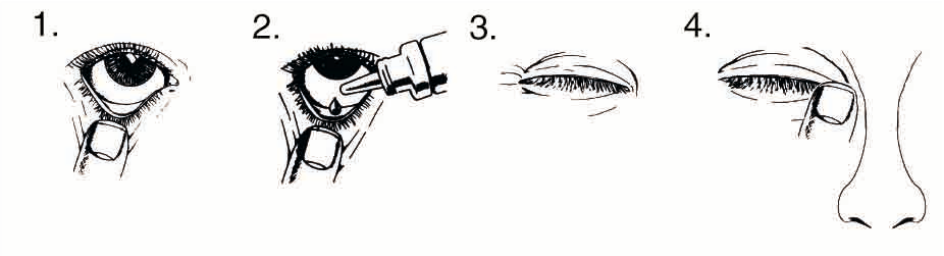
The usual dose is one drop of COMBIGAN, twice a day about 12 hours apart. Do not change the dose or stop taking it without speaking to your doctor.

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

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first begin to use it.

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 two minutes. This helps stop COMBIGAN getting into the rest of the body.

If a drop misses your eye, try again.

To avoid contamination, 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.

Your doctor will tell you how long your treatment with COMBIGAN will last. Do not stop treatment early because COMBIGAN should be used every day to work properly. If you have the impression that the effect of COMBIGAN is too strong or too weak, tell your doctor or pharmacist.

If you use more COMBIGAN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact

the nearest hospital or poison centre.

If you use more COMBIGAN than you should, it is unlikely to cause you any harm. Put your next drop in at the usual time. If you are worried, talk to your doctor or pharmacist.

If you forget to use COMBIGAN

If you forget to use COMBIGAN, use a single drop in each eye that needs treatment as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for forgotten individual doses.

If you stop using COMBIGAN

COMBIGAN should be used every day to work properly.

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

4. Possible side effects

COMBIGAN can have side effects. Not all side effects reported for COMBIGAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using COMBIGAN, please consult your doctor, pharmacist or other health care provider for advice.

If you experience any of the following side effects, please contact your doctor immediately:

- Heart failure (e.g. chest pain) or irregular heart rate;
- Increased or decreased heart rate or low blood pressure.

The following side effects may be seen with COMBIGAN:

Affecting the eye

Frequent side effects:

- Eye redness or burning
- Stinging or pain in the eye
- Allergic reaction in the eye or on the skin around the eye
- Small breaks in the surface of the eye (with or without inflammation)
- Swelling, redness or inflammation of the eyelid
- Irritation, or a feeling of something in the eye
- Itching of the eye and eyelid
- Follicles or white spots on the see-through layer which covers the surface of the eye
- Vision disturbance
- Tearing
- Eye dryness
- Sticky eyes

Less frequent side effects:

- Difficulty in seeing clearly
- Swelling or inflammation of the see-through layer which covers the surface of the eye
- Tired eyes
- Sensitivity to light
- Eyelid pain
- Whitening of the see-through layer which covers the surface of the eyes (cornea)
- Swelling or areas of inflammation under the surface of the eye
- Floaters in front of the eyes
- Separation of the gel that fills the eye from the back of the eye (retina)

Not known:

- Blurred vision

Affecting the body

Frequent side effects:

- High blood pressure
- Slow heart rate
- Depression
- Sleepiness
- Headache
- Light headedness
- Dry mouth
- Inflammation of the nose
- Nausea
- Diarrhoea
- General weakness

Less frequent side effects:

- Heart failure
- Irregular heart rate
- Low blood pressure
- Fainting
- Dry nose
- Taste disturbance

Not known:

- Increased or decreased heart rate
- Low blood pressure
- Face redness

Some of these effects may be due to an allergy to any of the ingredients. Additional side effects have been seen with brimonidine or timolol and therefore may potentially occur with COMBIGAN.

The following additional side effects have been seen with brimonidine:

- Inflammation within the eye, small pupils, difficulty sleeping, cold-like symptoms, shortness of breath, symptoms involving the stomach and digestion, general allergic reactions, skin reactions including redness, face swelling, itching, rash and widening of blood vessels.

COMBIGAN (brimonidine/timolol) is absorbed into the blood. Absorption of timolol, a beta-blocker component of COMGIBAN, may cause similar side effects as seen with “intravenous” and/or “oral” beta-blocking medicines.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of COMBIGAN.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

5. How to store COMBIGAN

- Store at or below 25 °C. Do not refrigerate.
- Store all medicines out of reach of children.
- Keep the bottle in the outer carton to protect from light.
- You should only use one bottle at a time.
- Do not use COMBIGAN after the expiry date which is stated on the label of the bottle and carton after EXP:. The expiry date refers to the last day of that month.
- You must throw away the bottle four weeks after you first opened it, even if there are still some drops left. This will help to prevent infections.
- Keep the dispensing container tightly closed when not in use.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COMBIGAN contains

- The active substances are brimonidine tartrate and timolol maleate.
- One ml of solution contains 2 mg of brimonidine tartrate and timolol maleate equivalent to 5 mg of timolol.
- The other ingredients are benzalkonium chloride 0,005 % m/v (a preservative); sodium phosphate monobasic monohydrate; sodium phosphate dibasic heptahydrate, hydrochloric acid or sodium hydroxide (to adjust pH) and purified water.

What COMBIGAN looks like and contents of the pack

COMBIGAN ophthalmic solution is a clear, greenish-yellow to light greenish-yellow solution,

essentially free from particulate matter in white plastic bottles with a screw-cap containing 5 ml of solution.

Holder of Certificate of Registration

AbbVie (Pty) Ltd

Building 7, Waterfall Corporate Campus

74 Waterfall Drive

Waterfall City

Midrand, 1685

South Africa

Tel: +27 (0) 11 031 1600

This leaflet was last revised in

17 February 2025

Registration number

A39/15.4/0464

Access to the corresponding Professional Information

For the professional information, please email medicalinfo.za@abbvie.com

CCDS v3.1, UK SmPC 25/11/2020