
PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using COMBIGAN.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medication is prescribed for the particular condition that you have. Never give this medication to others. It may harm them, even if their symptoms are the same as yours.

Scheduling Status

Schedule 3

Proprietary Name and Dosage Form

COMBIGAN ophthalmic solution (each ml of sterile solution contains brimonidine tartrate 2,0 mg and timolol maleate equivalent to timolol 5,0 mg)

WHAT COMBIGAN CONTAINS

Active ingredients: The medicinal ingredients in COMBIGAN are brimonidine tartrate and timolol maleate.

Preservative: Benzalkonium chloride 0,005 %

Inactive ingredients: Monobasic sodium phosphate monohydrate; dibasic sodium phosphate heptahydrate; purified water. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

WHAT COMBIGAN IS USED FOR

What kind of medication is COMBIGAN and how does it work

Your eye contains a clear, watery liquid that feeds the inside of the eye. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up.

COMBIGAN is a preserved eye drop solution that reduces the amount of fluid flowing into the eye and increasing the amount of fluid flowing out of the eye.

What is COMBIGAN for

COMBIGAN eye drops are used to reduce high pressure in the eye (intraocular pressure). This high pressure can lead to a disease called glaucoma. If the high pressure is not reduced, it could eventually damage your sight.

BEFORE YOU USE COMBIGAN

Before using COMBIGAN you should tell your doctor if

- You have any medical problems now or have had any in the past, especially asthma or other lung problems or heart problems.
- You have allergies to any medications.
- You wear contact lenses. The preservative in COMBIGAN, benzalkonium chloride, may be absorbed by soft (hydrophilic) contact lenses. Lenses should be removed prior to application of COMBIGAN and not re-inserted earlier than 15 minutes after use.
- You are pregnant or intend to become pregnant.
- You are breast-feeding or intend to breast-feed.
- You have or have had kidney or liver problems in the past.

Do not use COMBIGAN if you

- Are allergic to any of its components.
- Have asthma or have ever had asthma.
- Have chronic obstructive lung disease.
- Have certain heart disease or conditions.
- Have diabetes or are subject to low blood sugar levels without apparent cause.
- Are receiving monoamine oxidase (MAO) inhibitor therapy.
- Are breast feeding or pregnant.

Pregnancy and breast-feeding

Do not use COMBIGAN if you are pregnant or breast-feeding your baby. Tell your doctor if you have the intention of becoming pregnant or if you are planning to start breast-feeding.

Driving and using machinery

COMBIGAN may cause drowsiness and fatigue in some patients. Caution should be exercised when engaged in activities where mental alertness is required.

Using other medicines with COMBIGAN

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of COMBIGAN with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. This is particularly important if you are taking medicine to lower blood pressure or to treat heart disease.

INSTRUCTIONS ON HOW TO TAKE THIS MEDICINE

How to use COMBIGAN

- COMBIGAN was prescribed by your doctor to treat your specific medical problem and is for your use only. Do not share with others.
- The usual dose is one drop in the affected eye(s) in the morning and in the evening.

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- If you are using COMBIGAN with another eye drop, the drops should be instilled at least 10 minutes apart.
 - Your doctor may have told you to use COMBIGAN in a different way to that recommended in this leaflet. If so, follow your doctor's instructions about when and how to use the eye drops. Read the directions on your prescription label carefully. Ask your doctor or pharmacist to explain anything that you do not understand.
 - Do not change the dosage of the drug without consulting your physician. If you must stop treatment contact your physician immediately.
 - Do not start taking any other medicines unless you have discussed the matter with your physician.
 - If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelid, contact your physician immediately.
 - If you suspect that COMBIGAN is causing an allergic reaction, stop its use and contact your physician as soon as possible.
 - Avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.
 - Ocular solutions, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can be contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.
 - If you have ocular surgery or develop any other ocular condition (e.g. trauma or infection), you should immediately seek your physician's advice concerning the continued use of COMBIGAN.

Use in children

COMBIGAN is not recommended for children.

If you use more COMBIGAN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use COMBIGAN

If you forget to apply your eye drops at your normal time, simply apply them as soon as you remember. Then go back to the original schedule as directed by your doctor. Don't try to catch up on missed drops by applying more than one dose at a time.

SIDE EFFECTS

COMBIGAN can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Some common side-effects which may occur include:

- redness of eyes or inside of eyelids;
- irritation, itching or inflammation of eyes or eyelids;
- swelling of eye or eyelid;
- eye discharge;
- dry mouth;
- burning/stinging eye(s);
- blurred vision;
- feeling of something in the eye;
- headache;
- tiredness/drowsiness.

If these persist or cause you concern, consult your doctor. Be sure to tell your doctor (or pharmacist) promptly about any side effects or any unusual symptom.

STORAGE AND DISPOSAL INFORMATION

- Store below 25 °C and protect from light. Do not refrigerate.
- Keep all medicines out of reach and sight of children.
- The EXPIRY date is marked on the bottle. Do not use the ophthalmic solution past the expiry date. Do not use the solution for longer than 30 days after opening the bottle.
- Keep the dispensing container tightly closed when not in use.
- If COMBIGAN is swallowed, contact your doctor or poison control centre.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION

COMBIGAN ophthalmic solution is supplied in white, opaque plastic dropper bottles with a cap containing 5 ml.

IDENTIFICATION

COMBIGAN ophthalmic solution is a clear, greenish-yellow to light greenish-yellow solution, essentially free from particulate matter.

REGISTRATION NUMBER

A39/15.4/0464

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF
THE CERTIFICATE OF REGISTRATION**

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