

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **COMBIGAN®**

Brimonidine tartrate / timolol ophthalmic solution

Read this carefully before you start taking **COMBIGAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **COMBIGAN**.

What is COMBIGAN used for?

COMBIGAN is used to reduce pressure in the eye (called intraocular pressure, or IOP) in patients with conditions known as open-angle glaucoma and ocular hypertension. This high pressure can lead to a disease called glaucoma. If the high pressure is not reduced, it could eventually damage your sight.

How does COMBIGAN work?

COMBIGAN contains two different medicines (brimonidine and timolol) that both reduce the pressure inside the eye. COMBIGAN works by reducing the amount of fluid flowing into the eye and increases the amount of fluid flowing out of the eye.

Remember: This medication is prescribed for the particular condition you have. Do not give this medication to other persons or use it for any other condition.

What are the ingredients in COMBIGAN?

Medicinal ingredients: brimonidine tartrate and timolol (as timolol maleate)

Non-medicinal ingredients: Benzalkonium chloride 0.005% w/v as preservative, dibasic sodium phosphate heptahydrate, monobasic sodium phosphate monohydrate and purified water. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

COMBIGAN comes in the following dosage forms:

Ophthalmic solution, brimonidine tartrate 0.2% w/v and timolol (as timolol maleate) 0.5% w/v

Do not use COMBIGAN if you:

- are allergic to any of its components (See **What are the ingredients in COMBIGAN?**)
- have asthma or have ever had asthma
- have chronic obstructive lung disease (COPD)
- have certain heart diseases or conditions
- have receiving monoamine oxidase (MAO) inhibitor therapy

It should also not be used in children under the age of 2 years.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take COMBIGAN. Talk about any health conditions or problems you may have, including if you:

- have or have had kidney or liver problems in the past
- have had thyroid problems in the past
- have had eye problems in the past, such as choroidal detachment
- have had problems or develop problems with blood flow to the brain
- have any medical problems now or have had any in the past, especially asthma and other lung problems, heart problems or heart disease
- have diabetes or are subject to low blood sugar levels without apparent cause
- have myasthenia gravis or myasthenic symptoms (e.g., general weakness, double vision, droopy eyelid)
- are experiencing depression
- are pregnant or plan to become pregnant
- are breast-feeding or plan to breast-feed. Timolol passes in human breast milk. Your doctor will discuss with you how to feed your baby while taking COMBIGAN.
- are planning to have major surgery. If you will be administered an anesthetic, inform your healthcare professional before surgery that you are taking COMBIGAN.
- have or have had eye surgery.
- develop an eye condition due to infection injury.

Other warnings you should know about:

Immediately tell your healthcare professional if you:

- have or have had eye surgery
- develop an eye condition due to infection or injury.

Ask your healthcare professional for their advice on whether you should continue to use the COMBIGAN bottle.

Lung and heart problems

Serious lung and heart side effects, including death, have been reported in patients taking timolol systemically or by application to the eye. Tell your healthcare professional immediately if you have heart problems or lung problems such as asthma or COPD.

Driving and using machines:

COMBIGAN may cause you to become tired, drowsy or your vision may become blurry for some time. If any of these happen to you, wait until they go away before driving or using machines.

Pressure in your eye(s)

Your doctor should check the pressure in your eye(s) regularly.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with COMBIGAN:

- heart or blood pressure medications, such as beta-blockers
- calcium channel blockers
- catecholamine depleting drugs such as reserpine
- epinephrine
- tricyclic depressants
- quinidine
- clonidine
- alcohol
- central nervous system depressants
- antiarrhythmics (e.g. amiodarone)
- guanethidine
- digitalis glycosides

How to take COMBIGAN:

- If you are using COMBIGAN with another eyedrop, the drops should be used at least 10 minutes apart.
- Do not allow the tip of the dropper to touch your eye or any of the areas right around your eye, to avoid eye injury and contamination of eye drops. Touching other areas may contaminate the solution, and you may develop a serious eye infection.
- The preservative in COMBIGAN (benzalkonium chloride) may change the color of soft (hydrophilic) contact lenses. If you wear contact lenses, remove them before applying COMBIGAN and wait at least 15 minutes before putting them back in.

Usual dose:

The usual dose is one drop in the affected eye(s) in the morning and in the evening (about 12 hours apart).

Overdose:

Symptoms of overdose include dizziness, headache, shortness of breath, low blood pressure, slow heartbeat, difficulty breathing, and cardiac arrest. These symptoms may occur if the overdose is to the eyes, or if the contents of the bottle are accidentally swallowed.

If you think you, or a person you are caring for, have taken too much COMBIGAN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double dose.

What are possible side effects from using COMBIGAN?

These are not all the possible side effects you may have when taking COMBIGAN. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- blurred vision
- burning/stinging eye(s)
- diarrhea
- dizziness
- drowsiness
- dry eye(s)
- dry mouth
- eye pain
- headache
- itchy eye(s)
- nausea
- red / inflamed / itchy eyelids
- runny or dry nose
- swollen/inflamed/bloodshot eyes
- watery eyes
- weakness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Mental disorders: depression		✓	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness, chest pain, swelling in your ankles and legs, heart palpitations		✓	
UNCOMMON			
Severe allergic reaction: swelling of the mouth and throat, difficulty in breathing, hives, severe itching and rash			✓
Heart disorders: irregular or slow heartbeat, dizziness, weakness, difficulty breathing, fainting, chest pain or tightness.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Worsening of asthma, difficulty breathing			✓
Low blood sugar levels			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15 - 25°C). Protect from light.

Keep out of reach and sight of children.

If you want more information about COMBIGAN:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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