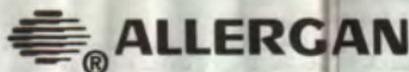


Combigan

2 mg/ml / 5 mg/ml eye drops, solution
brimonidine tartrate and timolol



Package Leaflet: Information For The User

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Combigan is and what it is used for
2. Before you use Combigan
3. How to use Combigan
4. Possible side effects
5. How to store Combigan
6. Further information

1. WHAT COMBIGAN IS AND WHAT IT IS USED FOR

Combigan is an eye drop that is used to control glaucoma. It contains two different medicines (brimonidine and timolol) that both reduce high pressure in the eye. Brimonidine belongs to a group of medicines called alpha-2 adrenergic receptor agonists. Timolol belongs to a group of medicines called beta-blockers. Combigan is prescribed to reduce high pressure in the eye when beta-blocker eye drops used alone are not enough.

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 and could eventually damage your sight. Combigan works by reducing the production of liquid and increasing the amount of liquid that is drained. This reduces the pressure inside the eye whilst still continuing to feed the eye.

2. BEFORE YOU USE COMBIGAN

Do not use Combigan:

- if you are allergic (hypersensitive) to any of the ingredients in Combigan
- if you have any breathing illnesses such as asthma or a history of asthma, or severe chronic obstructive lung disease.
- if you have heart problems such as heart beat disorders (unless controlled by a pacemaker) or heart weakness
- if the patient is less than 4 weeks old
- if you are taking monoamine oxidase (MAO) inhibitors or certain other antidepressant drugs

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

Take special care with Combigan:

Before you take this medicine, tell your doctor

- if you have now or have had in the past
 - depression or other psychiatric problems
 - heart or blood pressure problems
 - reduced or altered blood supply affecting the brain, legs or arms
 - diabetes or low blood sugar levels (hypoglycaemia)
 - overactivity of the thyroid
 - 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. 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 you need to have a general anaesthetic, tell your doctor that you are using Combigan.
- if you wear contact lenses. Do not put in the drops while you are wearing your lenses. Wait 10-15 minutes after using the drops before you put your lenses back in. The preservative in Combigan called benzalkonium chloride may cause eye irritation and is also known to discolour soft contact lenses.

Using other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant or planning to become pregnant. Combigan should not be used during pregnancy unless your doctor still recommends it.

Combigan should not be used if you are breast-feeding.

Driving and Using Machines

Combigan may cause drowsiness, tiredness or blurred vision in some patients.

Do not drive or use machinery until the symptoms have cleared. If you experience any problems, talk to your doctor.

3. HOW TO USE COMBIGAN

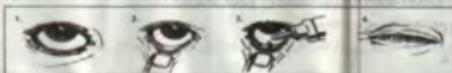
Always use Combigan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Combigan is not recommended for use in patients below 18 years.

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 use Combigan together with other eye drops, leave at least five minutes between putting in Combigan and the other 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 one minute.

If a drop misses your eye, try again.

To help prevent infection, 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.

If you use more Combigan than you should

Adults

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 Combigan is swallowed then you should contact your doctor.

Babies

A few incidences of overdose have been reported in babies (up to 4 weeks old) using brimonidine (one of the ingredients of Combigan). Signs include sleepiness, floppiness, low body temperature and breathing difficulties. If any of these occur, contact your doctor immediately.

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 a forgotten dose.

If you stop using Combigan

Combigan should be used every day to work properly.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Combigan can have side effects, although not everybody gets them.

The following eye side effects may be seen with Combigan. Eye redness, irritation, burning, stinging, itching of the eye and eyelid, an allergic reaction in the eye or on the skin around the eye, swelling and redness of the eyelid, blurred vision, a feeling of something in the eye, white spots under the eyelid, small breaks in the surface of the eye, with or without inflammation, sensitivity to light.

When using Combigan in the eye, small amounts can be absorbed into the blood and can cause side effects elsewhere in the body. These include depression, sleepiness, headache, high blood pressure, dry mouth, general weakness, an increase in blood-test results that show how your liver is working, light-headedness, heart failure, taste disturbances, dry nose and increased heart rate.

The following side effects have been seen with brimonidine or timolol and so may possibly be seen with Combigan. Inflammation of the iris, small pupils, reduced feeling in the eye, drooping eyelid, insomnia, chest pain, effects on the heart beat, low blood pressure, cold-like symptoms, shortness of breath, wheeziness, nausea, diarrhoea, heartburn, general allergic reactions, skin rash, cough, hair loss, nightmares, reduced sexual urge, memory loss, ringing in the ears and a worsening of myasthenia gravis (increased muscle weakness).

If you experience any side effect, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE COMBIGAN

Keep out of the reach and sight of children. Store Between 15°C and 25°C.

Keep the bottle in the outer carton to protect it 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 the 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. To help you remember, write down the date that you opened it in the space on the carton.

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.

6. FURTHER INFORMATION

What Combigan contains

- The active substances are brimonidine tartrate and timolol.
- One millilitre of solution contains 2 milligrams of brimonidine tartrate and timolol maleate equivalent to 5 milligrams of timolol.
- The other ingredients are benzalkonium chloride (a preservative), sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate and purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to bring the solution to the correct pH (a measure of the acidity or alkalinity of the solution).

What Combigan looks like and contents of the pack

Combigan is a clear, greenish-yellow eye drop solution in a plastic bottle with a screw-cap. Each bottle is about half full and contains 5 ml of solution.

Marketing Authorisation Holder and Manufacturer

Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, Co Mayo, Ireland

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists

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