

Combisopt®

(Dorzolamide + Timolol)

Preservative-Free, Sterile Ophthalmic Solution

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

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

1. What Combisopt® is and what it is used for

Combisopt® contains two medicines: dorzolamide and timolol.

- Dorzolamide belongs to a group of medicines called “carbonic anhydrase inhibitors”.
 - Timolol belongs to a group of medicines called “beta blockers”.
- These medicines lower the pressure in the eye in different ways. Combisopt® is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eye drop medicine used alone is not adequate.

2. What you need to know before you use Combisopt®

Do not use Combisopt®

- If you are allergic to dorzolamide hydrochloride, timolol maleate or any of the other ingredients of this medicine (listed in section 6).
- If you have now or had in the past respiratory problems, such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- If you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats).
- If you have severe kidney disease or problems, or a prior history of kidney stones.
- If you have excess acidity of the blood caused by a buildup of chloride in the blood (hyperchloraemic acidosis).

If you are not sure whether you should use this medicine, contact your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before using Combisopt®.

Tell your doctor about any medical or eye problems you have now or have had in the past:

- Coronary heart disease (symptoms can include chest pain or tightness, breathlessness, or choking), heart failure, low blood pressure.
- Disturbances of heart rate such as slow heartbeat.
- 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.
- Over-activity of the thyroid gland as timolol may mask signs and symptoms.

Tell your doctor before you have an operation that you are using Combisopt® as timolol may change effects of some medicines used during anaesthesia.

Also tell your doctor about any allergies or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing.

Tell your doctor if you have muscle weakness or have been diagnosed as having myasthenia gravis.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.

If you suspect that Combisopt® is causing an allergic reaction or hypersensitivity (for example, skin rash, severe skin reaction, or redness and itching of the eye), stop using this medicine and contact your doctor immediately.

Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including new or worsening symptoms.

When Combisopt® is instilled into the eye it may affect the entire body.

If you wear soft contact lenses, you should consult your doctor before using this medicine.

Use in children

There is limited experience with Combisopt® in infants and children.

Use in elderly

In studies with this medicine, the effects of this medicine were similar in both elderly and younger patients.

Use in patients with liver impairment

Tell your doctor about any liver problems you now have or have suffered from in the past.

Other medicines and Combisopt®

Combisopt® can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are:

- Taking medicine to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin).
- Taking medicines to treat a disturbed or irregular heartbeat such as calcium channel blockers, beta-blockers or digoxin.
- Using another eye drops that contains a beta-blocker.
- Taking another carbonic anhydrase inhibitor such as acetazolamide.
- Taking monoamine oxidase inhibitors (MAOIs) which are used to treat depression.
- Taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel.
- Taking narcotics such as morphine used to treat moderate to severe pain.
- Taking medicines to treat diabetes.
- Taking antidepressants known as fluoxetine and paroxetine.
- Taking a sulfa medicine.
- Taking quinidine (used to treat heart conditions and some types of malaria).

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Use in pregnancy

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

Use in breast-feeding

Do not use Combisopt® if you are breast-feeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines

No studies on the effects on the ability to drive or use machines have been performed. There are side effects associated with Combisopt®, such as blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well or your vision is clear.

3. How to use Combisopt®

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The appropriate dosage and duration of treatment will be established by your doctor.

The recommended dose is one drop in the affected eye(s) in the morning and in the evening.

If you are using this medicine with another eye drop, the drops should be instilled at least 10 minutes apart.

Do not change the dose of the medicine without consulting your doctor.

Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, wash your hands before using this medicine and keep the tip of the container away from contact with any surface. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

Combisopt® is a multidose HDPE dropper applicator that prevents content back contamination thanks to a silicon valve system and filtering air return into the bottle;

If you use more Combisopt® than you should

If you put too many drops in your eye or swallow any of the contents of the container, among other effects, you may become light-headed, have difficulty breathing, or feel that your heart rate has slowed. Contact your doctor immediately.

If you forget to use Combisopt®

It is important to use this medicine as prescribed by your doctor.

If you miss a dose, use it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule.

Do not use a double dose to make up for the forgotten dose.

If you stop using Combisopt®

If you want to stop using this medicine talk to your doctor first.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Combisopt® without speaking to your doctor.

Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction.

The frequency of possible side effects listed below is defined using the following convention:

- Very common (affects more than 1 user in 10)
- Common (affects 1 to 10 users in 100)
- Uncommon (affects 1 to 10 users in 1,000)
- Rare (affects 1 to 10 users in 10,000)
- Not known (frequency cannot be estimated from the available data)

The following side effects can be reported with Combisopt® or one of its components:

Very Common:

Burning and stinging of the eyes, unusual taste.

Common:

Redness in and around the eye(s), watering or itching of the eye(s), corneal erosion (damage to the front layer of the eyeball), swelling and/or irritation in and around the eye(s), feeling of having something in the eye, decreased corneal sensitivity (not realizing of getting something in the eye and not feeling pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness in the nose), feeling sick, also called nausea, weakness/tiredness, and fatigue.

Uncommon:

Dizziness, depression, inflammation of the iris, visual disturbances including refractive changes (in some cases due to withdrawal of medication to treat excessive contraction of the pupil of the eye), slow heartbeat, fainting, difficulty breathing (dyspnoea), indigestion, and kidney stones (often marked by a sudden onset of excruciating, cramping pain in their low back and/or side, groin, or abdomen).

Rare:

Systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), tingling or numbness of the hands or feet, trouble sleeping, nightmares, memory loss, an increase in signs and symptoms of myasthenia gravis (muscle disorder), decreased sex drive, stroke, temporary short sightedness which may resolve when treatment is stopped, detachment of the layer below the retina that contains blood vessels following from filtration surgery which may cause visual disturbances, drooping of the eyelids (making the eye stay half closed), double vision, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, ringing noises in your ear, low blood pressure, changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of feet and legs due to fluid buildup), oedema (fluid buildup), cerebral ischaemia (reduced blood supply to the brain), chest pain, palpitations (a quicker and/or irregular heartbeat), heart attack, Raynaud's phenomenon, swelling or coldness of your hands and feet and reduced circulation in your arms and legs, leg cramps and/or leg pain when walking (claudication), shortness of breath, feeling out of breath, runny or stuffed nose, nose bleed, constriction of the airways in the lungs causing difficulty in breathing, cough, throat irritation, dry mouth, diarrhea, contact dermatitis, hair loss, skin rash with white silvery colored appearance (psoriasisiform rash), Peyronie's disease (which may cause a curvature of the penis), allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, wheezing, or severe skin reactions (Stevens Johnson syndrome, toxic epidermal necrolysis).

Like other medicines applied into your eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed additional side effects include reactions seen within the class of beta-blockers when used for treating eye conditions.

Not known:

Low blood glucose levels, heart failure, a type of heart rhythm disorder, abdominal pain, vomiting, muscle pain not caused by exercise, sexual dysfunction.

5. How to store Combisopt®

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date on the container.

- The medicinal product should be stored below 30°C.

- In-use shelf life storage conditions:

90 days after first opening. Store below 25°C.

6. Contents of the pack and other information

What Combisopt® contains

- The active substances are dorzolamide and timolol.
- Each ml contains 22.26 mg Dorzolamide Hydrochloride equivalent to 20 mg Dorzolamide (2%) and 6.83 mg Timolol Maleate equivalent to 5 mg Timolol (0.5%).
- The other ingredients are: Hydroxyethylcellulose, mannitol, sodium citrate, sodium hydroxide.

What Combisopt® looks like and contents of the pack

Combisopt® is a Preservative-free, Sterile Ophthalmic Solution; 5ml bottle.

Combisopt® Preservative Free System Multidose Eyedropper was chosen as a selection of packaging systems suitable for ophthalmic preparations without preservatives.

It is designed with a one-way valve and a silicone plug acting as a venting system which permits air to enter into the venting system during use but prevents microbial ingress into the bottle and contamination of the contents.

Date of Revision: September 2019.

Manufactured by

Warsaw Pharmaceutical works Polfa S.A. Poland

Packed by

Benta S.A.L., Lebanon

This is a medicament

- A 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 for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Benta S.A.L.
Dbayeh - Lebanon

Prepared by: Nisrine Wehbeh

Date: September 2019

Color Shade number:

Product Name: Combisopt

Type: Package insert



Black

Die Cut N°: N/A

Die Cut Dimension: 160*200

Checked & Approved by:

Version N°: 2

Market: Lebanon-export countries

RA : _____ Date: _____

Specification: _____

Code: PI258

Biotechnology: _____ Date: _____

Content by: RA

Production: _____ Date: _____

Reason for Revision: _____

Marketing: _____ Date: _____

Delivered to Logistic Department:

Communication: _____ Date: _____

Name: _____ Date: _____

Quality Assurance: _____ Date: _____