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PACKAGE LEAFLET: INFORMATION FOR THE USER

MEDOX®

50 micrograms/ml + 5 mg/ml

Eye Drops, Solution

Latanoprost + Timolol



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

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

1. WHAT MEDOX IS AND WHAT IT IS USED FOR

Medox contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as "prostaglandin analogues". Timolol belongs to a group of medicines known as "beta-blockers".

Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

Medox is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you Medox when other medicines have not worked adequately.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MEDOX

Medox can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

Do not use Medox

- if you are allergic to Latanoprost or Timolol, beta-blockers, or any of the other ingredients of Medox (listed in section 6)
- if you have now or have had in 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)
- if you have serious heart problems or heart rhythm disorders
- if you are pregnant (or trying to become pregnant)
- if you are breast feeding.

Warning and precautions

Talk to your doctor or pharmacist before using Medox 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, low blood pressure (hypotension)
- disturbances of heart rate such as slow heart beat (bradycardia)
- 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
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- you know that you suffer from dry eyes
- you wear contact lenses. You can still use Medox but follow the instructions for contact lens wearers in Section 3
- you know that you suffer from angina (particularly a type known as Prinzmetal angina)
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV).

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

Other medicines and Medox

Medox 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.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Talk to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin

- analogues or prostaglandin derivatives
- Epinephrine
- Drugs used to treat high blood pressure such as calcium channel blockers, guanethidine, beta-blockers
- Antiarrhythmics (medications that normalise the heart rhythm) Digitalis glycosides (used to treat heart failure)
- Parasympathomimetic agents (e.g. for the treatment of high blood pressure)
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine.

Medox with food and drink

Normal meals, food or drink have no effect on when or how you should use Medox.

Pregnancy, breast-feeding and fertility

Do not use Medox if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

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

Driving and using machines

When you use Medox your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

Medox contains benzalkonium chloride

This medicine contains 5.64 micrograms benzalkonium chloride in each drop which is equivalent to 0.200 mg/ml. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. HOW TO USE MEDOX

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

Dosage

The recommended dose for adults (including the elderly) is one drop once a day in the affected eye(s).

Use in children and adolescents

Medox is not recommended for children or adolescents.

Do not use Medox more than once a day.

Contact lens wearers

If you wear contact lenses, you should remove them before using Medox. After using this product you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

Always wash your hands before applying eye drops.

Apply your eye drops in the following way:

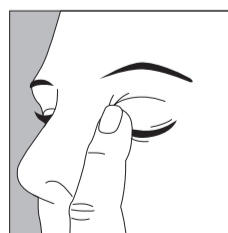
1. Remove protective cap.
2. Tilt your head back and look at the ceiling.
3. Gently pull the lower eyelid down until there is a small pocket, as illustrated in figure 1.

Figure 1.



4. Squeeze the upturned dropper bottle to release a drop into your eye.
5. Whilst keeping the affected eye closed, press your finger against the corner of the closed eye (the side where the eye meets the nose) as illustrated in figure 2 and hold for 2 minutes. This helps to stop Medox getting into the rest of the body.

Figure 2.



Avoid touching the dropper tip against your eye or anything else. Replace and tighten the cap straight after use.

If you use Medox with other eye drops

Wait at least 5 minutes between using Medox and using the other eye drops.

If you use more Medox than you should

If you put too many drops in your eye you

may experience some minor irritation in your eye and your eyes may water and turn red. This should pass but if you are worried contact your doctor for advice.

If you swallow Medox

If you swallow Medox accidentally you should contact your doctor for advice. If you swallow a lot of Medox you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

If you forget to use Medox

Carry on with the usual dosage at the usual time. Do not take a double dose to make up to the dose you have forgotten. If you are unsure about anything talk to 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 using the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Medox without speaking to your doctor.

Listed below are the known side effects of using Medox. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Medox might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using Medox.

The following are known side effects of using Medox:

Very common (may affect more than 1 in 10 people):

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use Medox in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Medox treatment is stopped.

Common (may affect up to 1 in 10 people):

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Uncommon (may affect up to 1 in 100 people):

- Headache
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye
- Skin rashes or itching (pruritus).
- Nausea
- Vomiting

Other side effects

Like other medicines applied into eyes, Medox (latanoprost and timolol) is absorbed into the blood.

This may cause similar side effects as seen with systemic beta-blocking agents. The incidence of side effects after using the eye drops is lower than when medicines are, for example, taken by mouth or injected.

Although not seen with Medox, the following additional side effects have been seen with the medicines in Medox (latanoprost and timolol) and therefore might occur when you use this product. Listed side effects include reactions seen within the class of beta-blockers (e.g.timolol) when used for treating eye conditions:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).
- 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, (angioedema) hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction (anaphylactic reaction).
- Low blood glucose levels (hypoglycaemia).
- Dizziness, difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucinations.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), unusual sensations like pins and needles, and headache.
- Swelling at the back of the eye (macular oedema), fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus)
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the

upper eyelid (making the eye stay half closed), double vision.

- Darkening of the skin around the eyes, changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), scarring of the surface of the eye.
- Whistling/ringing in the ears (tinnitus)
- Angina, worsening of angina in patients who already have heart disease. Slow heart rate, chest pain, palpitations (awareness of heart rhythm), oedema (fluid build up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), a type of heart rhythm disorder, heart attack, heart failure.
- Low blood pressure, poor blood circulation which makes the fingers and toes numb and pale, cold hands and feet.
- Shortness of breath, constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, asthma, worsening of asthma.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasis form rash) or worsening of psoriasis, skin rash.
- Joint pain, muscle pain not caused by exercise, muscle weakness, tiredness.
- Sexual dysfunction, decreased libido.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEDOX

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

Do not use this medicine after the expiry date, which is stated after EXP on the carton and bottle. The expiry date refers to the last day of that month.

Store the unopened bottle in a refrigerator (2°C - 8°C). After opening the bottle it is not necessary to store it in a refrigerator but do not store it above 25°C. After opening do not use this bottle for more than 4 weeks. When you are not using Medox, keep the bottle in the outer carton, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION WHAT MEDOX CONTAINS

What Medox contains

- The active substances are latanoprost and Timolol maleate. Each ml of solution contains 50 micrograms latanoprost and 6.8 mg timolol maleate equivalent to 5 mg timolol.
- The other ingredients are: Sodium chloride, Benzalkonium chloride, Sodium dihydrogen phosphate monohydrate, Disodium phosphate anhydrous, Hydrochloric acid solution (for adjustment to pH 6.0), Sodium hydroxide solution (for adjustment to pH 6.0) and Water for injections.

See section 2 "Medox contains benzalkonium chloride" for further information.

What Medox looks like and contents of the pack

Medox is a clear, colourless solution contained in a LDPE bottle and dropper applicator, PP screw cap, tamper evident LDPE overcap.

Pack sizes:
1 bottle × 2.5 ml
3 bottles × 2.5 ml
6 bottles × 2.5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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IG3 8BS. UK.

Manufacturer

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