Vigamox®

5 mg/ml eye drops

Novartis Pharma Schweiz AG

What are Vigamox eye drops and when are they used?

Vigamox eye drops contain the active substance moxifloxacin, a fluoroquinolone antibiotic effective against numerous bacteria that can cause eye infections.

Bacterial infections of the eye can affect the conjunctiva, tear ducts, cornea or eyelids. Vigamox eye drops are used to treat these bacterial eye infections and can be used only if prescribed by your doctor.

What else should I be aware of?

This medicine has been prescribed for you by your doctor to treat your current eye symptoms. The antibiotic contained in Vigamox eye drops is not effective against all microorganisms. Using wrong choice or wrong dose of antibiotic can cause complications. So never use Vigamox eye drops on your own initiative to treat other conditions or other people. Also, do not use the medicine for any future eye infections without consulting your doctor again.

Vigamox eye drops are intended exclusively for external use in the eye and must not be swallowed or injected.

Note for contact lens wearers:

Contact lenses must not be worn during treatment with Vigamox eye drops.

When should Vigamox eye drops not be used?

In known or suspected hypersensitivity (allergy) to any of the ingredients of Vigamox eye drops (e.g. moxifloxacin) or to other related antibiotics (quinolones).

When is caution advised when using Vigamox eye drops?

Consult your doctor immediately if you notice worsening of the infection or if new symptoms appear during treatment with Vigamox eye drops.

If you experience signs of intolerance such as difficulty breathing, swelling of the face, itching or tingling, interrupt treatment and immediately contact your doctor. If there is evidence of tendon inflamma-

tion, which can occur particularly in the elderly and if you are also taking corticosteroids, interrupt treatment and contact your doctor. If you temporarily experience blurred vi-

sion or discomfort after using Vigamox eye drops, you should wait until the symptoms have worn off before driving or operating machinery. Tell your doctor or pharmacist if you suf-

fer from any other diseases, have any allergies or are taking or applying to your eyes any other medicines (including medicines obtained without a prescription). Can Vigamox eye drops be used

by women who are pregnant or breast-feeding? Vigamox should not be used in pregnan-

cy unless it is absolutely necessary. It is not known whether the active ingredients of Vigamox pass into breast milk. Women using Vigamox for a prolonged period may have to stop breast-feeding. You should therefore ask your doctor for advice before using Vigamox eye drops if you are pregnant or think you may be pregnant, or if you are breast-feeding. How to use Vigamox eye drops

Adults and elderly patients over 65 years

Unless otherwise prescribed by your doc-

tor, the usual dose is 1 drop in the affected eye(s) 3 times a day (morning, noon and evening). Newborn and children:

Vigamox eye drops can be used in newborn babies and children. The dosage is the same as for adults.

Patients with reduced kidney or liver func-Vigamox eye drops can be safely used in

patients with reduced kidney or liver func-

Use Vigamox in both eyes only if your doctor tells you to. Do not change the prescribed dosage or length of treatment yourself. If you forget to use Vigamox eye

drops, apply the missed dose as soon as possible, then continue with the prescribed dosage schedule. If a drop miss-

your doctor or pharmacist.

es your eye, try again. If you are also using other eye drops, wait at least 5 minutes between applying Vigamox and the other drops. Eye ointments should be used last.

If you think the effect of your medicine is too weak or too strong, please talk to

What side effects can Vigamox eye drops have?

Active ingredients of eye medicines may enter the bloodstream. This means that side effects may occur not only in the eye, but also in other parts of the body.

The following side effects can occur when using Vigamox eye drops:

Common (in up to 10 in 100 people):

Eye pain, eye irritation. Uncommon (in up to 1 in 100 people):

Pinpoint defects in the upper layer of the cornea, dry eye, itchy eye, red eyes, swelling of the eyelid, taste changes, headache.

Rare (in up to 1 in 1000 people):

Corneal disorders, conjunctivitis, inflammation of the eyelids, eye swelling, blurred vision, reduced vision, redness of the eyelid, nose pain, sore throat, vomiting.

Also possible are:

Hypersensitivity to the medicine, dizziness, increased tear production, abnormal sensitivity to light, eye discharge, palpitations, nausea, itching, skin redness

Please consult your doctor or pharmacist immediately if these or any other side effects occur that you think may be connected to the use of Vigamox eye drops. You should inform your doctor or pharmacist if you notice any side effects not described here.

Further information

Instructions for use Sterility

To avoid possible microbial contamination of the eye drops, do not touch the dropper tip either with your hands or with your eyes. Close the bottle tightly after use and always keep it tightly closed.

Do not use after the expiry date (see "Use by" on pack). Do not use contents for longer than 4 weeks after opening the bottle.

Storage

Do not store bottle above 30°C. Keep out of the reach of children.

Overdose

The limited holding capacity of the conjunctival sac for eye drops practically precludes any overdosing of Vigamox eye

Poisoning due to accidentally swallowing the contents of the bottle is also practically impossible. Áfter the end of treatment, please bring

any bottle with remaining eye drops to your place of supply (doctor or pharmacist) for proper disposal.

Your doctor or pharmacist can give you additional information. These professionals have access to the full prescribing information.

What do Vigamox eye drops contain? 1 ml of Vigamox eye drops contains:

5 mg moxifloxacin (as hydrochloride 5.45 mg), inactive ingredients; sodium chloride, boric acid, hydrochloric acid and/ or sodium hydroxide (to adjust PH) and purified water.

Where can I obtain Vigamox eye drops? Which pack sizes are avail-Available only in pharmacies with a doc-

tor's prescription. Each prescription can be filled only once. Pack containing 5 ml dropper bottle.

Manufactured by Alcon-Couvreur B-2870 Puurs (Belgium)

for Novartis Pharma AG Basle, Switzerland This package leaflet was last re-

viewed in January 2016. This is a medicament

- A medicament is a product, which affects your health, and its consumption

- contrary to instructions is dangerous Follow strictly the doctor's prescription, the method of use and the instructions
 - of the pharmacist who sold the medica-- 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.

Keep medicaments out of reach

of children

Council of Arab Health Ministers Union of Arab Pharmacists