



Upneeq® (oxymetazoline hydrochloride ophthalmic solution), 0.1%

Frequently Asked Questions

UPNEEQ®
(oxymetazoline hydrochloride ophthalmic solution), 0.1%

Unless otherwise indicated, all images depict actor portrayals.

IMPORTANT SAFETY INFORMATION

What is UPNEEQ?

UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1% is a prescription eyedrop used to treat low-lying lids (acquired blepharoptosis) in adults.

What warnings and precautions are associated with UPNEEQ?

· Low-lying lids may be related to conditions such as stroke and/or brain aneurysm, Horner syndrome, myasthenia gravis, loss of the ability to move eye muscles, eye infection and eye tumors. Ask your doctor if you have any of these conditions.

Please see full Important Safety Information on pages 6 and 7.

Please see accompanying full Prescribing Information and Patient Information.

How does Upneeq work for low-lying (or droopy) eyelids?

The Müller's muscle is found in the eyelid and helps keep it at a certain height when the eye is open.¹ The active ingredient in Upneeq works by targeting the Müller's muscle, which makes it contract and lift the upper eyelid. This makes more of the iris and white of the eye visible, which makes the treated eye look bigger.²



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› HOW QUICKLY DOES UPNEEQ WORK?

It will depend on the person, but the clinical trials for Upneeq showed that most patients saw the highest lift in their eyelids in as little as 2 hours and the average lift that patients experienced was 1 mm.² One study showed that some patients saw a lift in their eyelids as soon as 5 to 15 minutes after their first dose.³

› HOW LONG DOES UPNEEQ LAST?

How long the effect lasts will vary from patient to patient, but the clinical trials for Upneeq showed that the greatest lift was seen at 2 hours and the lid remained lifted for up to 8 hours.^{2,4}

› WILL UPNEEQ STOP WORKING OVER TIME?

In clinical trials, patients took Upneeq once a day for 6 weeks. And in these clinical trials, there was no evidence that the effect from once-daily application of Upneeq decreased with continued use.^{2,4}

IMPORTANT SAFETY INFORMATION

What warnings and precautions are associated with UPNEEQ? (cont'd)

- UPNEEQ is a type of medication that may affect your blood pressure. If you have heart disease, uncontrolled high or low blood pressure, or feel faint at rest or when quickly standing up, you should call your doctor if your symptoms get worse.
- Patients with reduced blood flow to the brain or heart, or patients who experience eye or mouth dryness due to an immune system disorder (Sjögren's syndrome) should use care when taking UPNEEQ. Call your doctor immediately if you feel your symptoms may be getting worse.

› SHOULD UPNEEQ BE USED EVERY DAY?

Upneeq is indicated for daily use in the affected eye(s) with acquired ptosis. In clinical trials, the effect lasted from 6 to 8 hours.² Some patients choose to use Upneeq on select days when they would like to treat their droopy eyelids. However, to get results on a daily basis, Upneeq needs to be applied as a once-daily drop. Consult your healthcare provider if you have questions on using Upneeq.

› CAN UPNEEQ BE USED TWICE A DAY? WILL 2 DROPS OF UPNEEQ IN EACH EYE GIVE A BETTER RESULT?

Upneeq should be used once a day, 1 drop in each affected eye with acquired ptosis. There is no evidence to suggest that using it more often or using more than 1 drop will increase its effectiveness.²

› CAN I USE UPNEEQ IF I WEAR CONTACTS?

If you wear contact lenses, remove them before using Upneeq. You should wait at least 15 minutes before placing them back into your eyes.² If you wear contact lenses and have questions about also using Upneeq, consult your eyecare professional.

› CAN I USE UPNEEQ WITH OTHER EYE DROPS?

If you are using Upneeq with other eye (ophthalmic) medicines, you should wait at least 15 minutes between using Upneeq and the other medicines.² If you are using other eye drops and have questions about also using Upneeq, consult your eyecare professional.

› CAN EXTRA DROPS BE SAVED AND USED ON ANOTHER DAY?

No, you should not save any unused Upneeq. After you have applied the daily dose of medicine, throw away (dispose of) the single patient-use container and any unused Upneeq. Do not save any unused Upneeq. Do not let the tip of the Upneeq single patient-use container touch your eye or any other surfaces to avoid contamination or injury to your eye.²

IMPORTANT SAFETY INFORMATION

What warnings and precautions are associated with UPNEEQ? (cont'd)

- UPNEEQ may increase the risk of eye pressure due to fluid buildup (angle-closure glaucoma) in patients with untreated narrow-angle glaucoma. Call your doctor immediately if you feel increased pressure in your eye after using UPNEEQ.
- Do not let the tip of the UPNEEQ vial touch your eye or any other surface. This can help prevent eye injury or contamination. Each UPNEEQ vial is for one-time use and should be discarded after being used.

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› ARE THERE SIDE EFFECTS ASSOCIATED WITH UPNEEQ?

In clinical trials, Upneeq was proven to be safe and effective when used as directed. The most common adverse reactions with Upneeq (occurring in 1-5% of patients) were eye inflammation, eye redness, dry eye, blurred vision, eye pain at time of use, eye irritation, and headache. These are not all of the possible side effects of Upneeq. Tell your doctor if you have any side effect that bothers you or does not go away. Call your doctor for medical advice about side effects.²

In clinical trials, the majority of patients who used Upneeq reported that it caused “no discomfort” (95.5% of patients who used Upneeq for 6 weeks and 92.0% of patients who used Upneeq for 12 weeks), and almost all (94.9%) of those included in the clinical trials completed all study visits, which indicated that they were comfortable enough to continue daily dosing.⁵

› WHAT SHOULD I BE AWARE OF BEFORE USING UPNEEQ?

See Patient Counseling Information and Instructions For Use in the accompanying full Prescribing Information.

› IN CLINICAL TRIALS, DID UPNEEQ CHANGE EYE COLORATION?

No, there is no evidence from clinical trials that Upneeq affects eye color or skin pigmentation. The active ingredient of Upneeq, oxymetazoline, has been well studied and is known to primarily act on a muscle of the eyelid.²

› WHAT IF I HAVE GLAUCOMA?

Prior to starting Upneeq, you should be aware of the following information. Upneeq may increase the risk of eye pressure due to fluid buildup (angle-closure glaucoma) in patients with untreated narrow-angle glaucoma. Call your doctor immediately if you feel increased pressure in your eye after using Upneeq.² If you have any questions, you should consult your eye care professional.

If you are using Upneeq with other eye (ophthalmic) medicines, you should wait at least 15 minutes between using Upneeq and the other medicines.²

› WHAT IF I HAVE HIGH BLOOD PRESSURE?

Prior to starting Upneeq, you should be aware of the following

IMPORTANT SAFETY INFORMATION

What are the most common side effects of UPNEEQ?

The most common adverse reactions with UPNEEQ (occurring in 1-5% of patients) were eye inflammation, eye redness, dry eye, blurred vision, eye pain at time of use, eye irritation, and headache.

information. If you have heart disease, uncontrolled high or low blood pressure, feel faint at rest or when quickly standing up, you should call your doctor if your symptoms get worse.² If you have any questions about whether Upneeq is right for you, consult your doctor.

› WHAT IF I HAVE DRY EYE?

Prior to starting Upneeq, you should be aware of the following information. The most common adverse reactions with Upneeq (occurring in 1-5% of patients) were eye inflammation, eye redness, dry eye, blurred vision, eye pain at time of use, eye irritation, and headache. These are not all of the possible side effects of Upneeq. Tell your doctor if you have any side effect that bothers you or does not go away. Call your doctor for medical advice about side effects.² If you have any questions, you should consult your eye care professional.

› WHAT IF I HAVE SJOGREN'S SYNDROME?

If you have Sjogren's syndrome, you should use care when taking Upneeq.² Call your doctor immediately if you feel your symptoms may be getting worse. If you have any questions about whether Upneeq is right for you, consult your doctor.

› WHAT IF I HAVE HAD EITHER CATARACT SURGERY WITH OR WITHOUT AN INTRAOCULAR LENS OR LASIK?

Patients who have had cataract or LASIK surgery are not excluded from using Upneeq.² You should consult with your eye care provider if you have questions about using Upneeq following cataract, LASIK, or any other eye surgery.

IMPORTANT SAFETY INFORMATION

What should my doctor know about before prescribing me UPNEEQ?

- Your doctor should review your full medical history before prescribing UPNEEQ.
- UPNEEQ belongs to a class of medication (alpha-adrenergic agonists) that may affect your blood pressure. Use UPNEEQ carefully if you currently take an alpha-adrenergic agonist medication to treat heart disease or an enlarged prostate. Patients taking beta-blockers, or other medications to treat hypertension or an abnormal heartbeat, should also be careful when using UPNEEQ.
- Patients who use a certain class of antidepressant medication (monoamine oxidase inhibitors) should also be careful when using UPNEEQ, as it may affect the way your body absorbs the medication.

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Important Safety Information

› WHAT IS UPNEEQ?

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› WHAT WARNINGS AND PRECAUTIONS ARE ASSOCIATED WITH UPNEEQ?

- Low-lying lids may be related to conditions such as stroke and/or brain aneurysm, Horner syndrome, myasthenia gravis, loss of the ability to move eye muscles, eye infection and eye tumors. Tell your doctor if you have any of these conditions.
- UPNEEQ is a type of medication that may affect your blood pressure. If you have heart disease, uncontrolled high or low blood pressure, or feel faint at rest or when quickly standing up, you should call your doctor if your symptoms get worse.
- Patients with reduced blood flow to the brain or heart, or patients who experience eye or mouth dryness due to an immune system disorder (Sjögren's syndrome), should use care when taking UPNEEQ. Call your doctor immediately if you feel your symptoms may be getting worse.
- UPNEEQ may increase the risk of eye pressure due to fluid buildup (angle-closure glaucoma) in patients with untreated narrow-angle glaucoma. Call your doctor immediately if you feel increased pressure in your eye after using UPNEEQ.
- Do not let the tip of the UPNEEQ vial touch your eye or any other surface. This can help prevent eye injury or contamination. Each UPNEEQ vial is for one-time use and should be discarded after being used.

› WHAT ARE THE MOST COMMON SIDE EFFECTS OF UPNEEQ?

The most common adverse reactions with UPNEEQ (occurring in 1-5% of patients) were eye inflammation, eye redness, dry eye, blurred vision, eye pain at time of use, eye irritation, and headache.

› WHAT SHOULD MY DOCTOR KNOW ABOUT BEFORE PRESCRIBING ME UPNEEQ?

- Your doctor should review your full medical history before prescribing UPNEEQ.
- UPNEEQ belongs to a class of medication (alpha-adrenergic agonists) that may affect your blood pressure. Use UPNEEQ

carefully if you currently take an alpha-adrenergic antagonist medication to treat heart disease or an enlarged prostate. Patients taking beta-blockers, or other medications to treat hypertension or an abnormal heartbeat, should also be careful when using UPNEEQ.

- Patients who use a certain class of antidepressant medication (monoamine oxidase inhibitors) should also be careful when using UPNEEQ, as it may affect the way your body absorbs the medication.

These are not all of the possible side effects of UPNEEQ. Tell your doctor if you have any side effect that bothers you or does not go away. Call your doctor for medical advice about side effects.

To report side effects or product complaints, contact RVL Pharmaceuticals at 1-877-482-3788. You may also report side effects to the FDA by calling 1-800-FDA-1088 or visit www.fda.gov/medwatch.

This is a summary of the most important safety information for UPNEEQ. For more in-depth safety information, please review the full Prescribing Information for UPNEEQ.

References

1. Finsterer J. Ptosis: causes, presentation, and management. *Aesthetic Plast Surg.* 2003;27(3):193-204.
2. Upneeq (oxymetazoline hydrochloride ophthalmic solution), 0.1%. [Prescribing Information]. RVL Pharmaceuticals, Inc. 2021.
3. Bacharach J, Wirta DL, Smyth-Medina R, et al. Rapid and sustained eyelid elevation in acquired blepharoptosis with oxymetazoline 0.1%: randomized phase 3 trial results. *Clin Ophthalmol.* 2021;15:2743-2751.
4. Slonim CB, Foster S, Jaros M, et al. Association of oxymetazoline hydrochloride, 0.1%, solution administration with visual field in acquired ptosis: a pooled analysis of 2 randomized clinical trials. *JAMA Ophthalmol.* 2020;138(11):1168-1175.
5. Wirta DL, Korenfeld MS, Foster S, et al. Safety of once-daily oxymetazoline HCl ophthalmic solution, 0.1% in patients with acquired blepharoptosis: results from four randomized, double-masked clinical trials. *Clin Ophthalmol.* 2021;15:4035-4048.



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