

Oftaquix[®] Unit Dose 5mg/ml eye drops, solution in single-dose container (levofloxacin)

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The name of your medicine is Oftaquix Unit Dose 5mg/ml eye drops, solution in single-dose container but it will be referred to as Oftaquix throughout the remainder of this leaflet.

What is in this leaflet

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

1. What Oftaquix is and what it is used for

Levofloxacin is an antibiotic of the type called fluoroquinolones (sometimes shortened to quinolones). It works by killing some types of bacteria that can cause infections.

When levofloxacin is given in eye drops, it is used in children aged 1 year or over and in adults to treat bacterial infections that affect the front surfaces of the eye.

One type of infection in this area is called bacterial conjunctivitis, which is an infection of the covering of the front of the eye (conjunctiva).

Oftaquix is not recommended to be used in children aged below 1 year.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you use Oftaquix

Do not use Oftaquix

- if you are allergic to levofloxacin or other quinolones or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, ask your doctor or pharmacist first.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Oftaquix

- if an allergic reaction occurs even after a single dose stop using the medicine
- if you observe worsening of your eye symptoms during treatment, please contact your doctor as soon as possible
- if you do not see any sign of recovery within a certain treatment period agreed with your doctor, please contact your doctor as soon as possible
- generally, no types of contact lenses should be worn when the eye is infected.

Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking Oftaquix if you develop pain or swelling of the tendons (tendinitis).

Children and adolescents

The special warnings and precautions for using this medicine are the same in adults, adolescents and children aged ≥ 1 year.

Other medicines and Oftaquix

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines. In particular, tell your doctor or pharmacist if you are applying any other type of eye drop or eye ointment before you start to use Oftaquix.

If you are using other eye drops, you should wait at least 15 minutes between applying Oftaquix and any other type of eye drop.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Oftaquix eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the growing baby.

Although very small amounts of levofloxacin reach the blood and the breast milk, respectively, after instilling eye drops it is very unlikely that the eye drops would harm the growing baby.

Your doctor is informed about the potential risk and will advise you whether to take Oftaquix eye drops in this case.

Your fertility (ability to become pregnant or to father a child) is not impaired when you apply Oftaquix following its instructions for use.

Driving and using machines

Oftaquix has minor influence on the ability to drive and use machines. If the eye drops cause blurring of your sight when you use them, you should wait until this clears before driving or operating machinery.

3. How to use Oftaquix

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

Oftaquix eye drops are for ocular use and have to be applied to the outer surface of the eye.

For patients above 1 year of age, the recommended dose is as follows:

- DAYS 1 - 2
– Use one to two drops in the affected eye(s) every two hours.
- Use a maximum of 8 times per day.

DAYS 3 - 5

- Use one to two drops in the affected eye(s).
- Use a maximum of 4 times per day.

In elderly patients no adjustment of the recommended dose is required.

The usual total treatment course is five days. Your doctor will advise you how long to apply the drops.

If you are putting any other medicine in your eye, you should wait at least 15 minutes between applying the different types of drops.

Use in children and adolescents

No dosage modification is required in children ≥ 1 year old and in adolescents. Oftaquix is not recommended to be used in children aged below 1 year.

Before applying the drops:

If possible, ask someone else to apply the drops for you. Ask them to read these instructions with you before applying the drops.

- 1) Wash your hands.
- 2) Open the pouch along the dashed line.
- 3) Remove one single-dose container from the strip.
- 4) Put the remaining strip back in the pouch and fold the edge to close the pouch.
- 5) Make sure that the solution is in the bottom part of the single dose-container.



- 6) To open the container, twist off the tab



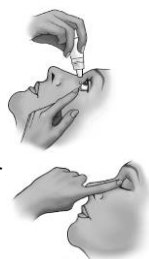
- 7) Tilt your head backwards while seated, or lie down on your back.

- 8) Place the tip of the container close to your eye.



9) Pull the lower eyelid downwards and look up.

10) Press the container slightly and let one drop fall into the space between the lower eyelid and the eye.



11) Close your eye for a moment. Press the inner corner of the eye with your index finger for about one minute. Thus you can prevent the eye drop from draining down the tear duct.

If another drop is needed, and when both eyes are to be treated, repeat steps 8 to 11.

Oftaquix eye drops should not be injected into the interior part of the eyeball.

For single use only. The eye drops should be used immediately after first opening the single dose container.

The contents of one single-dose container are sufficient for both eyes. Discard container with any remaining solution after single use.

If you use more Oftaquix than you should

If you use more Oftaquix than you should, flush the eye(s) with water and tell your doctor or pharmacist.

If you forget to use Oftaquix

If you forget to use the eye drops, put in the next dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you swallow Oftaquix by accident

The amount of levofloxacin in the provided amount of single-dose containers is too small to cause side effects. However, if you are concerned, tell your doctor or pharmacist, who will advise you on any necessary measures.

If you stop using Oftaquix earlier than instructed, it may delay the healing process.

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

4. Possible side effects

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

About one in ten people have a side effect when using Oftaquix. Most of these affect only the eye and may not last very long. If you have any severe or persistent side effect you should stop using these eye drops and seek urgent advice from your doctor.

It is possible, even though rare, to develop an allergic reaction to Oftaquix even after just one dose. You notice this because your eyes may become red or itchy, or the lids may be swollen. If this should happen, stop using Oftaquix and contact your doctor immediately.

Common side effects (may affect up to 1 in 10 users)

- burning feeling in the eye
- decreased vision or mucus in the eye.

Uncommon side effects (may affect up to 1 in 100 users)

- stinging or irritation of the eyes
- painful eyes
- dry or sore eyes
- swelling or redness (bloodshot eyes) of the conjunctivae (front covering of the eye)
- sensitivity to light
- itchy eyes
- sticky eyelids
- headache
- rash around the eye
- stuffed or runny nose.

Rare side effects (may affect up to 1 in 1,000 users)

- allergic reactions such as skin rash.

Very rare side effects (may affect less than 1 in 10,000 users)

- swelling and tightness in the throat
- breathing difficulty.

Additional side effects in children and adolescents

Frequency, type and severity of side effects in children and adolescents are expected to be the same as in adults.

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 at:

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 Oftaquix

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the single dose container, pouch and carton after "EXP". The expiry date refers to the last day of that month.
- Store in the original pouch in order to protect from light.
- You can use this medicine 3 months after first opening the pouch.
- Discard any unused single-dose container after that time.
- Discard the opened single-dose container with any remaining solution after first use immediately.
- Do not use this medicine if you notice insoluble parts in the solution.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- 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. Contents of the pack and other information

What Oftaquix contains

One ml contains 5 mg of levofloxacin (as hemihydrate).

Each single-dose container (0.3 ml) contains 1.5 mg of levofloxacin.

Also contains sodium chloride, diluted sodium hydroxide solution 20% or diluted hydrochloric acid 18% and water for injections.

What Oftaquix looks like and contents of the pack

Oftaquix is a clear, light yellow to light greenish-yellow solution, free of visible particulate matter.

Each pouch contains strip of 10 x 0.3ml single-dose containers, available in packs of 10 x 0.3ml or 30 x 0.3ml.

Manufactured by

Santen Oy, Kelloportinkatu 1, 33100 Tampere, Finland.

Procured from within the EU by the Product Licence Holder:

MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER.

Repackaged by MPT Pharma Ltd.

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Leaflet dated 17th February 2022

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Levofloxacin Unit Dose 5mg/ml eye drops, solution in single-dose container

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The name of your medicine is Levofloxacin Unit Dose 5mg/ml eye drops, solution in single-dose container but it will be referred to as Levofloxacin throughout the remainder of this leaflet.

What is in this leaflet

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

1. What Levofloxacin is and what it is used for

Levofloxacin is an antibiotic of the type called fluoroquinolones (sometimes shortened to quinolones). It works by killing some types of bacteria that can cause infections.

When levofloxacin is given in eye drops, it is used in children aged 1 year or over and in adults to treat bacterial infections that affect the front surfaces of the eye.

One type of infection in this area is called bacterial conjunctivitis, which is an infection of the covering of the front of the eye (conjunctiva).

Levofloxacin is not recommended to be used in children aged below 1 year.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you use Levofloxacin

Do not use Levofloxacin

- if you are allergic to levofloxacin or other quinolones or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, ask your doctor or pharmacist first.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Levofloxacin

- if an allergic reaction occurs even after a single dose stop using the medicine
- if you observe worsening of your eye symptoms during treatment, please contact your doctor as soon as possible
- if you do not see any sign of recovery within a certain treatment period agreed with your doctor, please contact your doctor as soon as possible
- generally, no types of contact lenses should be worn when the eye is infected.

Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking Levofloxacin if you develop pain or swelling of the tendons (tendinitis).

Children and adolescents

The special warnings and precautions for using this medicine are the same in adults, adolescents and children aged ≥ 1 year.

Other medicines and Levofloxacin

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist if you are applying any other type of eye drop or eye ointment before you start to use Levofloxacin.

If you are using other eye drops, you should wait at least 15 minutes between applying Levofloxacin and any other type of eye drop.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Levofloxacin eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the growing baby.

Although very small amounts of levofloxacin reach the blood and the breast milk, respectively, after instilling eye drops it is very unlikely that the eye drops would harm the growing baby.

Your doctor is informed about the potential risk and will advise you whether to take Levofloxacin eye drops in this case.

Your fertility (ability to become pregnant or to father a child) is not impaired when you apply Levofloxacin following its instructions for use.

Driving and using machines

Levofloxacin has minor influence on the ability to drive and use machines.

If the eye drops cause blurring of your sight when you use them, you should wait until this clears before driving or operating machinery.

3. How to use Levofloxacin

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

Levofloxacin eye drops are for ocular use and have to be applied to the outer surface of the eye.

For patients above 1 year of age, the recommended dose is as follows:
DAYS 1 - 2

- Use one to two drops in the affected eye(s) every two hours.
- Use a maximum of 8 times per day.

DAYS 3 - 5

- Use one to two drops in the affected eye(s).
- Use a maximum of 4 times per day.

In elderly patients no adjustment of the recommended dose is required.

The usual total treatment course is five days. Your doctor will advise you how long to apply the drops.

If you are putting any other medicine in your eye, you should wait at least 15 minutes between applying the different types of drops.

Use in children and adolescents

No dosage modification is required in children ≥ 1 year old and in adolescents. Levofloxacin is not recommended to be used in children aged below 1 year.

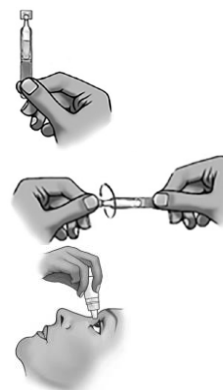
Before applying the drops:

If possible, ask someone else to apply the drops for you. Ask them to read these instructions with you before applying the drops.

- 1) Wash your hands.
- 2) Open the pouch along the dashed line.
- 3) Remove one single-dose container from the strip.
- 4) Put the remaining strip back in the pouch and fold the edge to close the pouch.
- 5) Make sure that the solution is in the bottom part of the single dose-container.

- 6) To open the container, twist off the tab

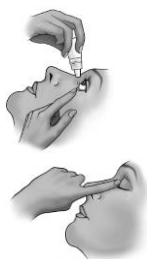
- 7) Tilt your head backwards while seated, or lie down on your back.
- 8) Place the tip of the container close to your eye.



9) Pull the lower eyelid downwards and look up.

10) Press the container slightly and let one drop fall into the space between the lower eyelid and the eye.

11) Close your eye for a moment. Press the inner corner of the eye with your index finger for about one minute. Thus you can prevent the eye drop from draining down the tear duct.



If another drop is needed, and when both eyes are to be treated, repeat steps 8 to 11.

Levofloxacin eye drops should not be injected into the interior part of the eyeball.

For single use only. The eye drops should be used immediately after first opening the single dose container.

The contents of one single-dose container are sufficient for both eyes. Discard container with any remaining solution after single use.

If you use more Levofloxacin than you should

If you use more Levofloxacin than you should, flush the eye(s) with water and tell your doctor or pharmacist.

If you forget to use Levofloxacin

If you forget to use the eye drops, put in the next dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you swallow Levofloxacin by accident

The amount of levofloxacin in the provided amount of single-dose containers is too small to cause side effects. However, if you are concerned, tell your doctor or pharmacist, who will advise you on any necessary measures.

If you stop using Levofloxacin earlier than instructed, it may delay the healing process.

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

4. Possible side effects

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

About one in ten people have a side effect when using Levofloxacin. Most of these affect only the eye and may not last very long. If you have any severe or persistent side effect you should stop using these eye drops and seek urgent advice from your doctor.

It is possible, even though rare, to develop an allergic reaction to Levofloxacin even after just one dose. You notice this because your eyes may become red or itchy, or the lids may be swollen. If this should happen, stop using Levofloxacin and contact your doctor immediately.

Common side effects (may affect up to 1 in 10 users)

- burning feeling in the eye
- decreased vision or mucus in the eye.

Uncommon side effects (may affect up to 1 in 100 users)

- stinging or irritation of the eyes
- painful eyes
- dry or sore eyes
- swelling or redness (bloodshot eyes) of the conjunctivae (front covering of the eye)
- sensitivity to light
- itchy eyes
- sticky eyelids
- headache
- rash around the eye
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Rare side effects (may affect up to 1 in 1,000 users)

- allergic reactions such as skin rash.

Very rare side effects (may affect less than 1 in 10,000 users)

- swelling and tightness in the throat
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Additional side effects in children and adolescents

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5. How to store Levofloxacin

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the single dose container, pouch and carton after "EXP". The expiry date refers to the last day of that month.
- Store in the original pouch in order to protect from light.
- You can use this medicine 3 months after first opening the pouch.
- Discard any unused single-dose container after that time.
- Discard the opened single-dose container with any remaining solution after first use immediately.
- Do not use this medicine if you notice insoluble parts in the solution.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- 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. Contents of the pack and other information

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What Levofloxacin looks like and contents of the pack

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Each pouch contains strip of 10 x 0.3ml single-dose containers, available in packs of 10 x 0.3ml or 30 x 0.3ml.

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