

EIKANCE 0.01% EYE DROPS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EIKANCE 0.01%?

EIKANCE 0.01% Eye Drops contain the active ingredient atropine sulfate monohydrate. They are used as a treatment for near sightedness in children aged from 4 to 14 years.

For more information, see Section 1. Why am I using EIKANCE 0.01%? in the full CMI.

2. What should I know before I use EIKANCE 0.01%?

Do not use if you have ever had an allergic reaction to atropine or any of the ingredients of the Eye Drops listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, use any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use EIKANCE 0.01%? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EIKANCE 0.01% and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use EIKANCE 0.01%?

- Use as directed by your Doctor. Do not use more than the number of drops he/she advises or use them more frequently than directed.
- Gently pull out the lower eyelid to form a sac. Allow one drop to fall into the sac without touching the eye with the dropper end of the container. To minimise absorption of the drug other than into the eye, close eyes and then apply gentle pressure to the tear duct for approximately one minute immediately after application.

More instructions can be found in Section 4. How do I use EIKANCE 0.01%? in the full CMI.

5. What should I know while using EIKANCE 0.01%?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using EIKANCE 0.01% Eye Drops. • Tell your doctor if you feel EIKANCE 0.01% Eye Drops are not helping your child's condition. • Tell your doctor if your child complains of problems in bright sunlight or with close work such as reading.
Things you should not do	• Do not use EIKANCE 0.01% Eye Drops if you have angle closure glaucoma, or a family history of glaucoma or other conditions unless your doctor tells you. • Do not give EIKANCE 0.01% Eye Drops to children under the age of 4 years. • Do not stop using EIKANCE 0.01% Eye Drops without telling your doctor.
Driving or using machines	• If you find it more difficult to focus, be careful before you drive or use any machine or tools.
Looking after your medicine	• Keep EIKANCE 0.01% Eye Drops where children cannot reach it. • Keep EIKANCE 0.01% Eye Drops in a cool, dry place where the temperature stays below 25°C and protect from light. Do not freeze or refrigerate.

For more information, see Section 5. What should I know while using EIKANCE 0.01% ? in the full CMI.

6. Are there any side effects?

The most common side effects of EIKANCE 0.01% Eye Drops are blurred vision, photophobia, allergy, sore, swollen, red and itchy eyes, headache and fatigue. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

EIKANCE 0.01%

Active ingredient: atropine sulfate monohydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using EIKANCE 0.01%. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EIKANCE 0.01%.**

Where to find information in this leaflet:

1. Why am I using EIKANCE 0.01%??
2. What should I know before I use EIKANCE 0.01%?
3. What if I am taking other medicines?
4. How do I use EIKANCE 0.01%?
5. What should I know while using ?
6. Are there any side effects?
7. Product details

1. Why am I using EIKANCE 0.01%?

EIKANCE 0.01% contains the active ingredient atropine sulfate monohydrate (atropine). EIKANCE 0.01% is an eye drop preparation used to deliver atropine directly to the eye for local activity. It reduces the rate of unwanted changes in the eye which may slow the progression of near sightedness (myopia).

EIKANCE 0.01% Eye Drops are used as a treatment to slow the progression of myopia in children aged from 4 to 14 years.

2. What should I know before I use EIKANCE 0.01%?

Warnings

Do not use EIKANCE 0.01% if:

- you are allergic to atropine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- if you have angle closure glaucoma or a family history of glaucoma.
- the expiry date printed on the pack has passed. If you use it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.
- if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are allergic to any other medicines or any foods, dyes or preservatives.
- have glaucoma or a family history of glaucoma

- are wearing contact lenses

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

EIKANCE 0.01% should not be used during pregnancy unless your doctor specifically tells you to.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with EIKANCE 0.01% and affect how it works these include

- Medicines to treat glaucoma
- Some medicines used to treat depression
- Some antihistamines
- Some medicines used to treat Parkinson's disease
- Some medicines used to treat mental illness
- Medicines used to treat muscle weakness
- Potassium citrate and potassium supplements

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EIKANCE 0.01%.

4. How do I use EIKANCE 0.01%?

How much to use

- Gently pull out the lower eyelid to form a sac. Allow one drop to fall into the sac without touching the eye with the dropper end of the container.
- To minimise absorption of the drug other than into the eye, close eyes and then apply gentle pressure to the tear duct for approximately one minute immediately after application.
- Follow the instructions provided and use EIKANCE 0.01% until your doctor tells you to stop.
- If you are wearing contact lenses, remove them before putting the drops in your eye.
- Wait 15 minutes before replacing your contact lenses.

think that it was not effective and change your treatment unnecessarily.

When to use EIKANCE 0.01%

- EIKANCE 0.01% should be used as directed by your Doctor. Do not use more than the number of drops he/she advises or use them more frequently than directed.
- It is important to use EIKANCE 0.01% exactly as directed.
- If you use less than you should, it may not work as well, and your medical condition may not improve.
- Using it more frequently than directed may not improve your condition any faster and may cause or increase side effects.

EIKANCE 0.01% eye drops should be administered as one drop to each eye at night

If you forget to use EIKANCE 0.01%

If you miss your dose at the usual time use it as soon as you remember and then return to your normal dosing time.

If you have trouble remembering when to use EIKANCE 0.01% Eye drops, ask your pharmacist for some hints.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

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

If you use too much EIKANCE 0.01%

While the risks associated with using too much EIKANCE 0.01% is small, if you think that you have used too much, you may need urgent medical attention.

Signs associated with too much atropine use include:

- Dry or burning mouth
- Difficulty in swallowing or talking
- Hot, dry skin
- Difficulty in passing urine

You should immediately:

- phone the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EIKANCE 0.01%?

Things you should do

Call your doctor straight away if you:

- feel EIKANCE 0.01% Eye Drops are not helping your child's condition.
- for any reason, you have not used the EIKANCE 0.01% Eye Drops as prescribed. Otherwise, your doctor may

Always discuss with your doctor any problems or difficulties during or after using EIKANCE 0.01% Eye Drops.

Remind any doctor, dentist or pharmacist you visit that your child is using EIKANCE 0.01%.

When EIKANCE 0.01% eye drops are first used, your child may experience greater sensitivity to sunlight. If this occurs, call your doctor. This effect usually decreases over time. The use of sunglasses or UV lenses in your glasses has been shown to help with this effect.

When using EIKANCE 0.01% eye drops, your child may find it more difficult to focus for close work or when reading. If this occurs, call your doctor to discuss options to help you manage this issue.

If you find it more difficult to focus, be careful before you drive or use any machine or tools.

Things you should not do

- Do not give EIKANCE 0.01% to anyone else even though their symptoms seem similar to yours.
- Do not use EIKANCE 0.01% for other conditions unless your doctor tells you. EIKANCE 0.01% Eye Drops have been prescribed for you for a specific condition. If you use it for another condition, it may not work or may make the condition worse.
- Do not give EIKANCE 0.01% to children under the age of 4 years.
- Do not stop using EIKANCE 0.01% suddenly. Discuss with your doctor if you plan to stop using this medicine.

Looking after your medicine

- A locked cupboard at least one and a half metres above the floor is a good place to store medicines.
- Keep EIKANCE 0.01% in a cool, dry place where the temperature stays below 25°C and protect from light.
- Do not freeze or refrigerate.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

EIKANCE 0.01% comes as single use containers. Discard any medicine left in the single use container after each dose administration.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Blurred vision • Eye irritation • Increased sensitivity to sunlight (photophobia) • Allergy • Sore, swollen, red and itchy eyes • Headache • Fatigue	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Systemic absorption • flushing, dryness of the skin, rapid and irregular pulse, fever, mental aberrations, psychosis and loss of neuromuscular coordination.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EIKANCE 0.01% contains

Active ingredient (main ingredient)	Atropine sulfate monohydrate 100 microgram/mL
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Other ingredients (inactive ingredients)	Citric acid monohydrate, sodium chloride and purified water. Hydrochloride acid or sodium hydroxide is used to adjust pH.
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Do not use this medicine if you are allergic to any of these ingredients.

What EIKANCE 0.01% Eye Drops look like

EIKANCE 0.01% eye drops are a clear, colourless solution filled into transparent 0.3 mL single-dose containers.

Strips of 5 single-dose containers are packed in an aluminium laminated foil sachet.

EIKANCE 0.01% eye drops are available in packs of 5, 30, 60 or 90 single-dose containers.

Not all pack sizes may be marketed. Who distributes EIKANCE 0.01%

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