Package leaflet: Information for the patient

AKANTIOR 0.8 mg/mL
eye drops, solution in single-dose container
polihexanide

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. See section 4.

What is in this leaflet

1. What AKANTIOR is and what it is used for

AKANTIOR contains the active substance polihexanide.

AKANTIOR is used in adults and children from 12 years of age to treat *Acanthamoeba* keratitis, *Acanthamoeba* is a parasite (tiny organism that lives inside humans and can cause disease) which can cause an infection resulting in keratitis (inflammation of the cornea, the clear layer in front of the eye). *Acanthamoeba* keratitis can cause severe defects on the surface of the cornea, including ulcers (open sores).

AKANTIOR damages the membrane (outer skin) of the *Acanthamoeba* parasite resulting in leakage of the cellular contents which destroys the cell. AKANTIOR also prevents the *Acanthamoeba* parasite from making copies of its DNA by interfering with enzymes (proteins) responsible for the replication process, which stops the growth and reproduction of the parasite in humans.

2. What you need to know before you use AKANTIOR

Do not use AKANTIOR
If you are allergic to polihexanide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using AKANTIOR.

Treatment with AKANTIOR may cause you mild to moderate eye discomfort (such as eye pain) and eye redness. In the case you are experiencing a severe eye reaction, contact your doctor.

Children and adolescents
AKANTIOR is not recommended in children under 12 years, as it has not been tested in this age group.

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

If you are using other eye drops, wait at least 5 minutes between applying AKANTIOR and the other drops. AKANTIOR should be administered last.

Pregnancy and breast-feeding

There is no experience of using AKANTIOR in pregnant women. AKANTIOR is not recommended during pregnancy. 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.

It is unknown whether AKANTIOR passes into breast-milk. Ask your doctor or pharmacist for advice before AKANTIOR treatment.

Driving and using machines
Your sight may become temporarily blurred after using AKANTIOR. Avoid driving or using machines until your sight is clear again.

AKANTIOR contains phosphates
This medicine contains 0.37 mg phosphates in each drop which is equivalent to 10.66 mg/mL. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use AKANTIOR

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

The treatment consists of two parts: intensive treatment that lasts for the first 19 days and continuation treatment that lasts from day 20.
The recommended dose is **1 drop** of AKANTIOR in the affected eye as follows:

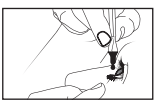
Starting intensive treatment (19 days)
- Apply one drop every hour (16 times a day), for the first five days (days 1 to 5)
- Apply one drop every 2 hours (8 times a day), for a further seven days (days 6 to 12)
- Apply one drop every 3 hours (6 times a day) , for a further seven days (days 13 to 19)

Continuation treatment
- Apply one drop every 4 hours (4 times a day), until there is no corneal inflammation or no evidence of infection (cured)
  Your doctor will advise you when to stop treatment.

Instructions for use
1) Wash your hands.
2) Open the aluminium sachet containing the single-dose containers.
3) Separate the single-dose container from the strip and put the unopened containers back into the sachet.

4) Open the single-dose container by twisting the upper part without pulling. Do not touch the tip after opening the container.

5) Tilt the head back. The single-dose container is now open. Keep the single dose container upright, and do not squeeze.
6) Use your finger to gently pull down the lower eyelid of your affected eye.
7) Invert the single-dose container and place the tip of the container close to your eye. Do not touch your eye or eyelid with the container tip.



8) Squeeze the single-dose container in order to administer only one drop, then release the lower eyelid.
9) Close your eye and press a finger against the corner of the affected eye by the side of your nose. Hold for 2 minutes.
10) Discard the single dose container after use.

If you use more AKANTIOR than you should
Put your next dose in at the usual time, as it is unlikely to cause you any serious harm.

If you forget to use AKANTIOR
Apply the next dose as usual. Do not use a double dose to make up for a forgotten dose.

If you stop using AKANTIOR
Use AKANTIOR as prescribed for best effect. Always tell your doctor if you are thinking about stopping the treatment.

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

4. Possible side effects

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

The majority of side effects generally occur at the treated eye.
Contact your doctor if you have a **severe eye reaction**.

The following side effects have been reported:
Very common (may affect more than 1 in 10 people)
- eye pain
- ocular hyperaemia (eye redness)

Common (may affect up to 1 in 10 people)
- corneal perforation (damage to the corneal surface)
- visual impairment
- ulcerative keratitis (inflammation or infection of the cornea)
- corneal epithelium defects (defects of outermost corneal layer)
- corneal infiltrates (immune response to corneal insult)
- punctuate keratitis (small breaks in the surface of the eye)
- tearing (watery eyes)
- conjunctival hyperaemia (redness of the conjunctiva)
- eye inflammation
- eye irritation
- photophobia (unpleasant eye sensitivity to light)
- conjunctival papillae (inside of eyelid gets red, swollen and irritated)
- eye pruritus (itchy eyes)
- eye discharge
- eye swelling
- foreign body sensation in the eye
- discomfort in the eye
- dry eye
- conjunctivitis (inflammation of the outermost layer of the eye)
- eye infection
- condition aggravated (disease worsening)
- product intolerance (hypersensitivity to the medicine)
- application site reactions such as pain
- application site reactions such as discomfort
- application site reactions such as pruritus (itching)
- persistent epithelial defect (persistent loss of outermost corneal layer after injury)
- toxicity to various agents
- corneal transplant required

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: https://www.hpra.ie/. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store AKANTIOR

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

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month of the unopened product.

This medicine does not require any special storage conditions.

After opening the sachet, the single-dose containers have to be used within 28 days. After this period, the unused single-dose containers must be discarded.

The contents of the single dose container must be used immediately after opening and any remaining content should be discarded.

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

6. Contents of the pack and other information

What AKANTIOR contains

- The active substance is polihexanide. Each mL of solution contains 0.8 mg of polihexanide.
- The other ingredients are sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium chloride and purified water.

AKANTIOR contains phosphates (see section 2).

What AKANTIOR looks like and contents of the pack

AKANTIOR eye drops, solution in single-dose container (eye drops) is a clear and colourless solution in a single-dose container.

The single-dose containers are moulded in 5 sealed units strip, which in turn are wrapped in a polyester/aluminium/polyethylene sachet and packaged inside a carton box.

Pack sizes:

- 20 single-dose containers
- 30 single-dose containers
- multipack containing 120 (4 packs of 30) single-dose containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

SIFI S.p.A.
Via Ercole Patti, 36
95025 Aci Sant'Antonio (CT)
Italy

This leaflet was last revised in 08/2024

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Detailed and updated information on this product is available by scanning the QR code included in the package leaflet and outer carton with a smartphone/device. The same information is also available on the following URL: https://qr.sifigroup.com/akantior/

Scan: