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Akantior (*polihexanide*)

An overview of Akantior and why it is authorised in the EU

What is Akantior and what is it used for?

Akantior is an eye medicine used in adults and children aged 12 years and older for the treatment of *Acanthamoeba* keratitis, a rare and serious eye infection that mainly affects people who wear contact lenses.

Acanthamoeba keratitis is caused by a single-celled organism called *Acanthamoeba* that affects the cornea (the transparent layer in front of the eye that covers the pupil and iris). If left untreated, *Acanthamoeba* keratitis, can lead to severe complications, including vision loss or the need for corneal transplant.

Acanthamoeba keratitis is rare, and Akantior was designated an 'orphan medicine' (a medicine used in rare diseases) on 14 November 2007. Further information on the orphan designation can be found here: EU/3/07/498

Akantior contains the active substance polihexanide.

How is Akantior used?

Akantior can only be obtained with a prescription and should only be prescribed by a doctor with experience in the diagnosis and treatment of *Acanthamoeba* keratitis.

Akantior is available as an eye-drop solution. The treatment schedule includes an intensive 19-day treatment phase and a continuation phase. During the intensive phase, Akantior is always given during the day as one drop in the affected eye, every hour, 16 times a day in the first 5 days, then one drop, every two hours, 8 times a day, for the next 7 days and then one drop, every three hours, 6 times a day, for the next 7 days.

After completing the intensive phase, patients begin the continuation phase where Akantior is given as one drop in the affected eye every 4 hours 4 times a day, until the patient is cured (based on healing of cornea, absence of corneal inflammation or infection) or for a maximum of 12 months.

For more information about using Akantior, see the package leaflet or contact your healthcare provider.

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How does Akantior work?

The active substance in Akantior, polihexanide, works in two ways. It binds to and damages the outer layer (membrane) of the *Acanthamoeba* cell, causing the release of the contents of the cell, leading to its death. Once polihexanide passes through the outer layer of the *Acanthamoeba* cell, it also damages the genetic material in the cell by interacting with the structural support that holds the cell's DNA strands together. This prevents the *Acanthamoeba* cell from replicating (making copies of itself).

What benefits of Akantior have been shown in studies?

The proportion of patients cured from infection after treatment with Akantior was higher when compared to data from the literature on patients that had not received a treatment targeting the *Acanthamoeba* organism.

In a main study, adults and children with *Acanthamoeba* keratitis with no previous history of treatment targeting the *Acanthamoeba* organism were treated with either Akantior given together with placebo (a dummy treatment) or an eye medicine containing a lower dose of polihexanide, compared to the dose in Akantior, in combination with propamidine (an antiseptic that is also used to treat eye infections caused by bacteria).

The results from the group treated with Akantior were also compared to data from previous studies, identified in the literature, involving patients with *Acanthamoeba* keratitis who did not receive treatment targeting the *Acanthamoeba* organism. Twelve months after starting the study, around 85% of patients (56 out of 66 patients) given Akantior with placebo were cured of the disease 30 days after stopping treatment compared to 89% of patients (54 out of 61 patients) given the combination of lower dose polihexanide and propamidine. As identified from literature, around 20% of patients (11 out of 56 patients) who did not receive treatment targeting the *Acanthamoeba* organism were cured.

What are the risks associated with Akantior?

For the full list of side effects and restrictions with Akantior, see the package leaflet.

The most common side effects with Akantior (which may affect more than 1 in 10 people) include eye pain and ocular hyperaemia (redness of the eye).

The most serious side effects with Akantior (which may affect up to 1 in 10 people) include corneal perforation (small tear or hole in the eye's clear front layer), corneal damage requiring a transplant (replacement of the eye's damaged clear front layer with healthy tissue) and visual impairment (reduced vision).

Why is Akantior authorised in the EU?

Although there were some uncertainties with the design of the main study, Akantior was found to be effective at treating *Acanthamoeba* keratitis. In its evaluation, the European Medicines Agency took into consideration that no medicines were authorised for the treatment of *Acanthamoeba* keratitis at the time of approval of Akantior and that most side effects in the main study were mild or moderate in severity.

The Agency therefore decided that Akantior's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Akantior?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Akantior have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Akantior are continuously monitored. Suspected side effects reported with Akantior are carefully evaluated and any necessary action taken to protect patients.

Other information about Akantior

Akantior received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Akantior can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Akantior.

This overview was last updated in 08-2024.