



COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

**PUBLIC SUMMARY OF
POSITIVE OPINION FOR ORPHAN DESIGNATION
OF
polihexanide
for the treatment of *Acanthamoeba* keratitis**

On 14 November 2007, orphan designation (EU/3/07/498) was granted by the European Commission to S.I.F.I. Società Industria Farmaceutica Italiana S.p.A., Italy, for polihexanide for the treatment of *Acanthamoeba* keratitis.

What is *Acanthamoeba* keratitis?

Acanthamoeba are organisms made up of a single cell, which can cause an eye disease. These organisms live and survive in many different places such as air, soil and water environments. From these sources, they can gain access to contact lens solutions and contact lenses. Tap water used to clean lenses is a common source of such an infection. The *Acanthamoeba* may be on the lens or in the cleaning solutions. If lenses are left in the eyes for long periods of time, these amoebae can multiply and cause damage to the eye (such as rips and ulcers).

Acanthamoeba keratitis is a chronically debilitating condition and may result in loss of sight in the infected eye.

What are the methods of treatment available?

No satisfactory methods exist that were authorised at the time of application.

What is the estimated number of patients affected by the condition*?

Based on the information provided by the sponsor and previous knowledge of the Committee, *Acanthamoeba* keratitis was considered to affect less than 0.1 in 10,000 persons in the European Union, which, at the time of designation, corresponded to about 5,000 persons in total.

How is this medicinal product expected to act?

Polihexanide is a disinfectant that is active against bacteria and *Acanthamoeba*. It is contained in solutions for the preservation of contact lenses, and other medical or industrial products. There are published studies in scientific journals, in which the efficacy of polihexanide in *Acanthamoeba* keratitis has been evaluated.

What is the stage of development of this medicinal product?

The effects of polihexanide were evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials in patients with *Acanthamoeba* keratitis had been initiated.

* Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed based on data from the European Union (EU 27), Norway, Iceland and Lichtenstein. This represents a population of 498,000,000 (Eurostat 2006). This estimate is based on available information and calculations presented by the sponsor at the time of the application.

Polihexanide was not authorised anywhere in the world for *Acanthamoeba* keratitis or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 12 September 2007 a positive opinion recommending the grant of the above-mentioned designation.

Opinions on orphan medicinal products designations are based on the following cumulative criteria: (i) the seriousness of the condition, (ii) the existence or not of alternative methods of diagnosis, prevention or treatment and (iii) either the rarity of the condition (considered to affect not more than five in ten thousand persons in the Community) or the insufficient return of development investments.

Designated orphan medicinal products are still investigational products which were considered for designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of the quality, safety and efficacy will be necessary before this product can be granted a marketing authorisation.

For more information:

Sponsor's contact details:

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**Translations of the active ingredient and indication in all EU languages
and Norwegian and Icelandic**

Language	Active Ingredient	Indication
English	Polihexanide	Treatment of <i>Acanthamoeba</i> keratitis
Bulgarian	Полихексанид	Лечение на кератит, причинен от акантамеба
Czech	Polyhexanid	Léčba acanthamoebové keratitidy
Danish	Polihexanid	Behandling af acanthamøbe keratoconjunctivitis
Dutch	Polihexanide	Behandling af <i>Acanthamoeba</i> keratitis
Estonian	Polihexaniid	<i>Acanthamoeba</i> keratiidi ravi
Finnish	Poliheksanidi	Akantamebakeratiitin hoito
French	Polihexanide	Traitement de la k�ratite caus�e par l' <i>acanthamoeba</i>
German	Polihexanid	Behandlung von <i>Acanthamoeba</i> -Keratitis
Greek	Πολιεξανίδη	Θεραπεία της κερατίτιδας από <i>Acanthamoeba</i>
Hungarian	Polihexanid	<i>Acanthamoeba</i> keratitis kezel�se
Italian	Poliesanide	Trattamento della cheratite da <i>Acanthamoeba</i>
Latvian	Poliheksan�ds	Akantamebi�zes kerat�ta �rst�šana
Lithuanian	Poliheksanidas	Keratito, sukelta <i>Acanthamoeba</i> , gydymas
Maltese	Polihexanide	Kura tal-keratite ikkawzata mill- <i>Acanthamoeba</i>
Polish	Poliheksanid	Zapalenie rog�wki wywo�ane przez <i>Acanthamoeba</i>
Portuguese	Polihexanida	Tratamento da ceratite por <i>acanthamoeba</i>
Romanian	Polihexanid�	Tratamentul keratitei produse de <i>Acanthamoeba</i>
Slovak	Polyhexanid	Liečba <i>Acanthamoeba</i> keratitis
Slovenian	Poliheksanid	Zdravljenje akatamebnega keratitisa
Spanish	Polihexanida	Tratamiento de la queratitis por <i>Acanthamoeba</i>
Swedish	Polihexanid	Bahandling av acantham�ba-keratit
Norwegian	Poliheksanid	Behandling av acantham�be-keratitt
Icelandic	P�lihexan�d	Me�fer� � <i>Acanthamoeba</i> gl�erub�lgu