



24 April 2015
EMA/COMP/440430/2007 Rev.1
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Ciclosporin for the treatment of Herpes simplex virus stromal keratitis

First publication	1 July 2008
Rev.1: sponsor's name change	24 April 2015
Disclaimer Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 29 October 2007, orphan designation (EU/3/07/489) was granted by the European Commission to Novagali Pharma SA, France, for ciclosporin for treatment of Herpes simplex virus stromal keratitis.

In March 2015, Novagali Pharma SA changed name to SANTEN SAS.

What is *Herpes simplex virus stromal keratitis*?

Herpes simplex virus stromal keratitis is an inflammatory disease of the cornea (the central transparent tissue in the front of the pupil, in the eye) associated with infection by the Herpes simplex virus. This inflammation leads to dense scarring of the cornea. The condition is chronically debilitating due to possible loss of sight.

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

At the time of designation, *Herpes simplex virus stromal keratitis* affected less than 1.6 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 80,000 people^{*}, and is below the ceiling for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

^{*}Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 27), Norway, Iceland and Liechtenstein. At the time of designation, this represented a population of 500,300,000 (Eurostat 2007).



What treatments are available?

Various medicinal products were authorised for the treatment of Herpes simplex virus stromal keratitis in the Community at the time of submission of the application for orphan drug designation.

Ciclosporin might be of potential significant benefit for the treatment of Herpes simplex virus stromal keratitis. Ciclosporin might help to achieve better overall control of the condition. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

Ciclosporin is an immunosuppressor, in other words it acts by inhibiting (blocking) the cells from the defence system involved in the inflammation process. The inflammation in stromal keratitis is thought to be the most important cause of the damage caused to the corneal structure by the viral infection.

What is the stage of development of this medicine?

The effects of ciclosporin were evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials in patients with Herpes simplex virus stromal keratitis were initiated.

Ciclosporin was not authorised anywhere in the world for the treatment of Herpes simplex virus stromal keratitis, or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 12 September 2007 recommending the granting of this designation.

Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the EU) or insufficient returns on investment.

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

For more information

Sponsor's contact details:

SANTEN SAS
Bâtiment Genavenir IV
1, Rue Pierre Fontaine
F-91058-Evry cedex
France
Tel. +33 1 69 87 40 20
Fax +33 1 69 87 40 30
E-mail: contact@santen.com

For contact details of patients' organisations whose activities are targeted at rare diseases see:

- [Orphanet](#), a database containing information on rare diseases, which includes a directory of patients' organisations registered in Europe;
- [European Organisation for Rare Diseases \(EURORDIS\)](#), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.

Translations of the active ingredient and indication in all official EU languages¹, Norwegian and Icelandic

Language	Active Ingredient	Indication
English	Ciclosporin	Treatment of <i>Herpes simplex</i> virus stromal keratitis
Bulgarian	Циклоспорин	Лечение на предизвикан от херпес симплекс стромален кератит
Czech	Ciclosporin	Léčba stromální keratitidy způsobené virem Herpes Simplex
Danish	Ciclosporin	Behandling af Herpes simplex virus stromal keratitis
Dutch	Ciclosporine	Behandeling van <i>Herpes simplex</i> virus stromale keratitis
Estonian	Tsüklosporiin	<i>Herpes Simplex</i> viiruse tekitatud sarvkesta strooma põletik
Finnish	Siklosporiini	Herpes Simplex-viruksen aiheuttaman strooman keratiitin hoito
French	Ciclosporine	Traitement de la kératite stromale à virus herpès simplex
German	Ciclosporin	Behandlung einer durch das Herpes-simplex-Virus verursachten stromalen Keratitis
Greek	Κυκλοσπορίνη	Θεραπεία της στρωματικής κερατίτιδας από ιό του απλού έρπητα
Hungarian	Cyclosporin	Herpes simplex vírus okozta stromalis keratitis kezelése
Italian	Ciclosporina	Tattamento della cheratite stromale da virus dell'herpes simplex
Latvian	Ciklosporīns	<i>Herpes Simplex</i> vīrusa izraisīta radzenes stromas iekaisuma ārstēšana
Lithuanian	Ciklosporinas	Stromos keratitui, sukeltam paprastosios pūslelinės viruso, gydymas
Maltese	Ciclosporin	Kura tal-keratite stromali ikkaġunata mill-virus <i>Herpes simplex</i>
Polish	Cyklosporyna	Leczenie zapalenia istoty właściwej rogówki wirusem opryszczki pospolitej
Portuguese	Ciclosporina	Tratamento da ceratite estromal causada pelo vírus do herpes simples
Romanian	Ciclosporină	Tratamentul keratitei stromale determinată de virusul Herpes simplex
Slovak	Cyklosporín	Liečba stromálnej keratitídy vyvolanej <i>Herpes simplex</i>
Slovenian	Ciklosporin	Zdravljenje stromalnega keratitisa, ki ga povzroča virus Herpes simplex
Spanish	Ciclosporina	Tratamiento de la queratitis del estroma por virus del herpes simple
Swedish	Ciklosporin	Behandling av stromakeratit orsakad av herpes simplex-virus
Norwegian	Ciklosporin	Behandling av stromal keratitt forårsaket av herpes simplex virus
Icelandic	Cíklósporín	Meðferð við grunnfrumubólgu í glæru af völdum Herpes simplex veiru

¹ At the time of designation