



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Diphenylcyclopropenone for the treatment of alopecia totalis

First publication	23 April 2009
Rev.1: sponsor's change of address	6 April 2011
Rev.2: withdrawal from the Community Register	11 September 2013
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.	

Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in July 2013 on request of the Sponsor.

On 29 June 2006, orphan designation (EU/3/06/379) was granted by the European Commission to Orfagen, France, for diphenylcyclopropenone for the treatment of alopecia totalis.

What is alopecia totalis?

Alopecia totalis is a disease characterised by massive hair loss (more than 90%) of the scalp. It affects patients in an acute form (loss of hair within weeks) or in a slower form (hair loss that can progress for up to two years). Usually patients do not recover from the hair loss and the condition becomes chronic. Alopecia totalis can affect patients of both sexes and of any age. Patients suffering alopecia totalis report psychological consequences (distress, sadness) that are particularly severe in children and women.

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

At the time of designation, alopecia totalis affected not more than 2.5 in 10,000 people in the European Union (EU). This was equivalent to a total of not more than 117,000 people*, and is below

*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 25), Norway, Iceland and Liechtenstein. At the time of designation, this represented a population of 468,900,000 (Eurostat 2006).



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).

What treatments are available?

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

How is this medicine expected to work?

Hair loss seen in alopecia totalis is thought to be caused by cells of the immune system (body's own defence mechanism against infection and disease) attacking the hair follicles. Diphenylcyclopropenone can act as local irritant and trigger local sensitization, which is an allergic reaction to itself. By doing this, it is thought to mount an immune response and produce populations of immune cells that oppose the action of the autoreactive cells that destroy hair loss. This way it is thought to allow hair growth locally. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, clinical trials in patients with alopecia totalis were completed. The sponsor of the application plans to conduct further clinical studies.

Diphenylcyclopropenone was not authorised anywhere worldwide for alopecia totalis 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 16 May 2006 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:

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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	Diphenylcyclopropenone	Treatment of alopecia totalis
Czech	Difenylcyclopropenon	Léčba alopecie totalis
Danish	Difenylcyklopropenon	Behandling af alopecia totalis
Dutch	Diphenylcyclopropenon	Behandeling van alopecia totalis
Estonian	Difenüülsüklopropenoon	<i>Alopecia totalise ravi</i>
Finnish	Difennyylisyklopropenooni	Täydellisen alopesian hoitoon
French	Diphénylcyclopropénone	Traitement de l'alopecie totale.
German	Diphenylcyclopropenon	Behandlung der Alopecia totalis
Greek	Διφαινυλοκυκλοπροπενόνη	Αγωγή κατά της ολικής αλωπεκίας
Hungarian	Difenilciklopropenon	Alopecia totalis kezelése
Italian	Difenilciclopropenone	Trattamento dell'alopecia totale
Latvian	Difenilciklopropenons	Pilnīgas plikgalvības [<i>alopecia totalis</i>] ārstēšana
Lithuanian	Difenilciklopropenonas	Visiško nuplikimo gydymas
Polish	Difenylcyklopropenon	Leczenie łysienia całkowitego skóry głowy
Portuguese	Difenilciclopropenona	Tratamento da alopecia totalis
Slovak	Difenylcyklopropenón	Liečba alopeciae totalis
Slovenian	Difenilciklopropenon	Zdravljenje alopecije totalis
Spanish	Difenilciclopropenona	Tratamiento de la alopecia total
Swedish	Difenylcyklopropenon	Behandling av alopecia totalis
Norwegian	Difenylcyklopropenon	Behandling av alopecia totalis
Icelandic	Tvífenýlcýklóprópenón	Til meðferðar á alskalla (alopecia totalis)

¹ At the time of designation