



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF

fluocinolone acetonide (prolonged-release intravitreal implant) for the treatment of non-infectious uveitis affecting the posterior segment of the eye

On 7 March 2005, orphan designation (EU/3/05/261) was granted by the European Commission to Bausch & Lomb (UK) Ltd, United Kingdom, for fluocinolone acetonide (prolonged-release intravitreal implant) for the treatment of non-infectious uveitis affecting the posterior segment of the eye.

The sponsorship was transferred to Bausch & Lomb Ireland in October 2006.

What is non-infectious uveitis affecting the posterior segment of the eye?

The term uveitis covers clinical symptoms of inflammation of the uvea, the middle layer of the eye - between the sclera and retina. The medicinal product, which is the subject of this designation, is a drug delivery system containing fluocinolone acetonide, which is surgically implanted behind the surface of the eye. The condition is, therefore, limited to uveitis affecting the back of the eye.

There are a number of different causes for uveitis. It may result from an infection or it may be related to an autoimmune disease (with or without involvement of other parts of the body), where a reaction to an individual's own tissues (in this case in the eye) occurs because the body's defence system rejects other parts of the body. Trauma to the eye can also lead to uveitis. In many cases the cause may be unknown. This medicinal product would only target the non-infectious posterior uveitis.

Uveitis can affect one eye or both eyes and may cause varying degrees of discomfort or pain, with or without blurring of vision. Non-infectious uveitis affecting the posterior segment of the eye is chronically debilitating as it may lead to structural damage to the tissues in the eye, cataracts and sight loss.

What are the methods of treatment available?

Various medicinal products were available for the treatment of non-infectious uveitis affecting the posterior segment of the eye and were authorised in some Member States in the Community at the time of submission of the application for orphan drug designation.

Fluocinolone acetonide (prolonged-release intravitreal implant) might be of potential significant benefit for the treatment of non-infectious uveitis affecting the posterior segment of the eye. The benefit will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

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

According to the information provided by the sponsor, non-infectious uveitis affecting the posterior segment of the eye was considered to affect between 13,800 to 46,000 persons in the European Union.

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How is this medicinal product expected to act?

Fluocinolone acetonide is a corticosteroid and is expected to reduce inflammation and suppress autoimmunity. The product is composed of a drug delivery system that is surgically implanted into the posterior segment of the eye to deliver fluocinolone acetonide over a prolonged length of time (target of 3 years).

What is the stage of development of this medicinal product?

The effects of fluocinolone acetonide (prolonged-release intravitreal implant) were evaluated in experimental models. At the time of submission of the application for orphan designation, clinical trials in patients with non-infectious uveitis affecting the posterior segment of the eye were ongoing.

Fluocinolone acetonide (prolonged-release intravitreal implant) was not marketed anywhere worldwide for treatment of non-infectious uveitis affecting the posterior segment of the eye, at the time of submission. On 31 July 2000, orphan designation of flucinolone was granted in the United States for treatment of uveitis involving the posterior segment of the eye.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 13 January 2005 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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*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 25), Norway, Iceland and Lichtenstein. This represents a population of 459,700,000 (Eurostat 2004). This estimate is based on available information and calculations presented by the sponsor at the time of the application.

Patients' associations contact points:

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

Language	Active Ingredient	Indication
English	Fluocinolone acetonide (prolonged-release intravitreal implant)	Treatment of non-infectious uveitis affecting the posterior segment of the eye
Czech	Fluocinolon acetonid (s prodlouženým uvolňováním ze sklivcového implantátu)	Léčba neinfekční uveitidy postihující zadní segment oka
Danish	Fluocinolonacetamid (intravitrealt depot impantat)	Behandling af ikke-infektiøs uveitis, som påvirker øjets bageste segment
Dutch	Fluocinolonacetonide (intravitreaal implant met verlengde vrijstelling)	De behandeling van niet-besmettelijke uveitis in het achterste deel van het oog
Estonian	Fluotsinoloonatsetoniid (prolongeeritud toimega intravitreaalne implantaat)	Silma tagumist segmenti hõlmava mitteinfektsioosse uveiidi ravi
Finnish	Fluokinoloniasetonidi (intravitreaalinen depotimplantti)	Silmän takasegmentin käsittävään, infektoitumattoman uveitin hoitoon
French	Acétonide de fluocinolone (Implant intra vitré à action prolongée)	Le traitement des uvéites non-infectieuses affectant le segment postérieur de l'œil
German	Fluocinolonacetamid (intravitreales Implantat mit verzögerter Freisetzung)	Behandlung von nichtinfektiöser Uveitis des hinteren Augensegments.
Greek	Ακετονίδιο της φλουοκινολόνης (Μόσχευμα παρατεταμένης απελευθέρωσης εντός του υαλώδους σώματος του οφθαλμού)	Θεραπευτική αγωγή για τη μη λοιμώδη ραγοειδίτιδα που επηρεάζει το οπίσθιο τμήμα του οφθαλμού
Hungarian	Fluocinolon acetamid (elhúzódó hatóanyagleadású üvegtesti implantátum)	A szem hátsó szegmensét érintő, nem fertőzőes eredetű uveitis kezelése
Italian	Acetonide di fluocinolone (Trapianto intravitreo a rilascio prolungato)	Il trattamento dell'uveite non infettiva con coinvolgimento del segmento posteriore dell'occhio
Latvian	Fluocinolona acetoniīds (ilgstošas darbības intravitreāls implants)	Neinfekcioza mugurējā uveīta ārstniecība
Lithuanian	Fluocinolono acetonidas (prolonguoto atpalaidavimo vidinis stiklakūnio implantas)	Neinfekcinio uveito gydymas, apimantis užpakalinį akies segmentą
Polish	Acetonid fluocinolonu (implant do ciała szklistego o przedłużonym uwalnianiu)	Leczenie nieinfekcyjnego zapalenia błony naczyniowej w obrębie tylnego odcinka oka

Portuguese	Acetonido de fluocinolona (implante intravítreo de libertação prolongada)	O tratamento de uma uveíte não infecciosa que afecta o segmento posterior do olho
Slovak	Fluocinolón acetonid (Intravitrealný implantát s predĺženým uvoľňovaním)	Liečba neinfekčnej uveitídy zasahujúcej zadnú časť oka
Slovenian	Fluocinolon acetonid (intravitrealni implant s podaljšanim sproščanjem)	Zdravljenje nenalezljivega uveitisa, ki zajema posteriorni del očesa
Spanish	Acetónido de fluocinolona (implante intravítreo de liberación prolongada)	El tratamiento de uveítis no infecciosas que afectan al segmento posterior del ojo
Swedish	Fluokinolonacetonid (intravitreal depot implant)	Behandling av icke-infektiös uveit som berör ögats bakre segment
Norwegian	Fluocinolonacetonid (Intravitreal depot-implantat)	Behandling av ikke-smittsom uveitt, som påvirker bakre del av øyet
Icelandic	Flúocínólón acetóníð (til forðalyfsígræðslu í glerhlaup augans).	Meðferð við æðahjúpsbólgu sem ekki er rakin til sýkingar og leggst á aftari hluta augans