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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Titanium dioxide and bisoctrizole for the treatment of UV-A and visible light-induced photosensitivity disorders (chronic actinic dermatitis, cutaneous porphyrias, actinic prurigo and solar urticaria)

First publication	1 July 2005
Rev.1: sponsor's change of address	6 April 2011
Rev.2: withdrawal from the Community Register	23 July 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Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in July 2013 on request of the Sponsor.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 3 March 2005, orphan designation (EU/3/05/262) was granted by the European Commission to Orfagen, France, for titanium dioxide and bisoctrizole for the treatment of UV-A and visible light-induced photosensitivity disorders (chronic actinic dermatitis, cutaneous porphyrias, actinic prurigo and solar urticaria).

What are UV-A and visible light-induced photosensitivity disorders (chronic actinic dermatitis, cutaneous porphyrias, actinic prurigo and solar urticaria)?

UV-A and visible light-induced photosensitivity disorders include various skin diseases, which have in common that exposure to UV rays or even to visible light results in an abnormal skin reaction (photosensitivity). This can produce skin lesions such as redness, scratches, blisters and scarring. Among the skin diseases induced by the UV-A and the visible light, chronic actinic dermatitis, actinic prurigo and solar urticaria appear without an underlying cause while cutaneous porphyria occurs in people having an underlying metabolic disease.



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

At the time of designation, UV-A and visible light-induced photosensitivity disorders affected approximately 3.5 in 10,000 people in the European Union (EU). This was equivalent to a total of around 163,000 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).

What treatments are available?

Different methods are used for the treatment of these photosensitivity disorders depending on the nature of the skin disease. Avoidance or minimization of light exposure remains the current main treatment for all these disorders. At the time of submission of the application for orphan drug designation, additional treatments such as anti-inflammatory, emollients and antiallergic products were commonly used. Also phototherapy (exposure of the skin to a specific light regimen), plasmapheresis (the washout of certain harmful substances from plasma) and phlebotomy (removal of small amounts of blood from the veins) were used in specific situations. Titanium dioxide and bisoctrizole might be of potential significant benefit for the treatment of the above-specified photosensitivity disorders. The 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?

Titanium dioxide and bisoctrizole cream is expected to combine a high sun blocking protection (UV-B and UV-A range) together with an extended protection to normal visible light. To obtain this maximum photoprotection, the cream contains a mineral compound (titanium dioxide) and a chemical filter (bisoctrizole).

What is the stage of development of this medicine?

The effects of titanium dioxide and bisoctrizole were evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials in patients with UV-A and visible light-induced photosensitivity disorders were ongoing.

Titanium dioxide and bisoctrizole is not marketed anywhere worldwide for the treatment of UV-A and visible light-induced photosensitivity disorders (chronic actinic dermatitis, cutaneous porphyrias, actinic prurigo and solar urticaria) 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 13 January 2005 recommending the granting of this designation.

*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 466,600,000 (Eurostat 2005).

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	Titanium dioxide and bisoctrizole	Treatment of UV-A and visible light-induced photosensitivity disorders (chronic actinic dermatitis, cutaneous porphyrias, actinic prurigo and solar urticaria)
Czech	Oxid titaničitý a bisoktrizol	Léčba fotosenzitivních poruch vyvolaných UV-A a viditelným světlem (chronická aktinodermatitida, kožní porfyrie, aktinické prurigo, solární kopřivka)
Danish	Titandioxid Bisoctrizol	Behandling af fotosensivitets sygdomme forårsaget af UV-A og synligt lys (kronisk aktinisk dermatitis, kutan porfyri, aktinisk prurigo og soludløst urtikaria)
Dutch	Titaniumdioxide en bisoctrizol	Behandeling van aandoeningen veroorzaakt door fotosensibilisatie aan UV-A en zichtbaar licht (chronische actinische dermatitis, cutane porfyria, actinische prurigo en solaire urticaria)
Estonian	Titaandioksiid ja bisoktrizool	UV-A-kiirgusest ja nähtavast valgusest tingitud valgustundlikkushäirete ravi (krooniline aktiiniline dermatiit, nahaporfüüria, aktiiniline pruriigo ja päikese urtikaaria)
Finnish	Titaanidioksidi ja bisoctrizoli	UVA-valon ja näkyvän valon aiheuttamien valoherkkyysoireiden (krooninen aktiivinen dermatiitti, ihoporfyriat, aktiivinen kutina ja aurinkoihottuma) hoito
French	Dioxyde de Titane et Bisoctrizole	Traitement des maladies avec photosensibilité aux UV-A et à la lumière visible (dermatite actinique chronique, porphyries cutanées, prurigo actinique, urticaire solaire)
German	Titandioxid Bisoctrizol	Behandlung von durch UV-A-Strahlung und sichtbares Licht induzierter Photosensibilität (chronische aktinische Dermatitis, Hautporphyrie, aktinischem juckendem Ausschlag, Sonnenurticaria)
Greek	Διοξειδίο του Τιτανίου και Βισοκτριζόλη	Θεραπεία διαταραχών φωτοευαισθησίας (χρόνια ακτινική δερματίτιδα, δερματική πορφύρια, ακτινική κνήφη, και ηλιακή κνίδωση) επαγόμενης από ορατή και UV-A ακτινοβολία
Hungarian	Titán-dioxid és bisoctrizol	Az UV-A és a látható fény által kiváltott fényérzékenység kezelése (krónikus acne okozta dermatitis, porphyria cutanea, acne okozta prurigo és napfény urticaria esetén)
Italian	Titanio diossido e Bisoctrizolo	Trattamento dei disturbi di fotosensibilità agli UV-A ed alla luce visibile (dermatite cronica attinica, porfirie cutanee, prurigo attinica, orticaria solare)
Latvian	Titāna dioksīds un bisoktrizols	UV-A un redzamās gaismas inducēto fotosensitivitātes traucējumu (hronisks aktīniskis dermatīts, ādas porfirija, aktīniska nieze, saules nātrene) ārstēšana
Lithuanian	Titano dioksidas ir bisoktrizolas	UV-A ir matomos šviesos spindulių sukulto fotojautrumo ligų (lėtinio aktinio dermatito, odos porfirijos, aktinio niežulio ir saulės spindulių sukeltos urtikarijos) gydymas

¹ At the time of designation

Language	Active Ingredient	Indication
Polish	Tytanu dwutlenek i bisoktrizol	Leczenie zaburzeń wywołanych nadwrażliwością na światło w paśmie widzialnym i UV-A (przewlekłe trądzikowi zapalenie skóry, porfiria skórna, świerzbączka trądzikowi i pokrzywka słoneczna)
Portuguese	Dióxido de titânio e Bisoctrizole	Tratamento das doenças de fotossensibilidade induzida pela luz visível e UV-A (dermatite actínica crónica, porfírias cutâneas, prurigo actínico e urticária solar).
Slovak	Oxid titaničitý a bisoktrisol	Liečba ochorení s poruchou fotosenzibility spôsobenou UV-A žiarením a viditeľným svetlom (chronická aktinická dermatitída, kožné porfýrie, aktinické prurigo a solárna urtikária)
Slovenian	Titanov dioksid in bisoktrizole	Zdravljenje fotosenzitivnosti inducirane z vidno in UV-A svetlobo (kronični aktinični dermatitis, kožne porfirije, aktinični prurigo, sončna urtikarija).
Spanish	Dióxido de titanio y bisoctrizol	Tratamiento de los trastornos por fotosensibilidad inducidos por la luz visible y por los UV-A (dermatitis actínica crónica, porfírias cutáneas, prurito actínico y urticaria solar)
Swedish	Titandioxid och bisoctrisol	Behandling av fotosensibilitets sjukdomstillstånd orsakade av UV-A och synligt ljus (kronisk aktinisk dermatit, kutan porfyrier, aktinisk prurigo, solutlöst urtikaria)
Norwegian	Titandioksid og bisoctrizol	Behandling av fotosensitive sykdomstilstander induisert av UV-A og synlig lys (kronisk aktinisk dermatitt, kutane porfyrier, aktinisk prurigo, solutløst urtikaria)
Icelandic	Títaníum tvíoxíð bisoctrizól	Meðferð við ljósnæmiskvillum tengdum útfjólubláu- og sýnilegu ljósi (langvinn aktínísk húðbólga, húð porfyría, aktínískt prurigo og sólar urticaria).