



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

(-)-17-(cyclopropylmethyl)-3,14 β -dihydroxy-4,5 α -epoxy-6 β -[N-methyl-trans-3-(3-furyl) acrylamido] morphinan hydrochloride (intravenous use) for the treatment of uremic pruritus

On 11 September 2002, orphan designation (EU/3/02/115) was granted by the European Commission to Toray Europe Limited, United Kingdom, for (-)-17-(cyclopropylmethyl)-3,14 β -dihydroxy-4,5 α -epoxy-6 β -[N-methyl-trans-3-(3-furyl) acrylamido] morphinan hydrochloride (intravenous use) for the treatment of uremic pruritus.

Toray Europe Limited changed name to Toray International U.K. Limited in January 2008.

What is uremic pruritus?

Uremic pruritus is a severe and persisting form of itching which occurs in some patients whose kidneys are not functioning properly. Because of kidney failure, these patients have to undergo a process of filtering of accumulated waste products from the blood (haemodialysis) or the peritoneum, a membrane which lines the abdomen (peritoneal dialysis). Uremic pruritus can be severe and impair the patients' quality of life.

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

At the time of designation, uremic pruritus affected approximately 3.5 in 10,000 people in the European Union (EU)*. This is equivalent to a total of around 132,000 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?

There were no authorised products for the treatment in the Community. Products which are frequently used in the common forms of itching have only limited efficacy in many patients.

*Disclaimer: The number of patients affected by the condition is estimated and assessed for the purpose of the designation, for a European Community population of 377,000,000 (Eurostat 2001) and may differ from the true number of patients affected by the condition.



How is this medicine expected to work?

It seems that the itching is linked to an imbalance in opium-similar substances that are produced naturally in the brain. (-)-17-(cyclopropylmethyl)-3,14 β -dihydroxy-4,5 α -epoxy-6 β -[N-methyl-trans-3-(3-furyl) acrylamido] morphinan hydrochloride (intravenous use) is expected to activate a receptor (called kappa-receptor). Stimulation of this receptor of the central nervous system would alleviate the uremic pruritus.

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 uremic pruritus were ongoing.

(-)-17-(cyclopropylmethyl)-3,14 β -dihydroxy-4,5 α -epoxy-6 β -[N-methyl-trans-3-(3-furyl) acrylamido] morphinan hydrochloride (intravenous use) had not been marketed anywhere worldwide for uremic pruritus 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 1 August 2002 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	(-)-17-(cyclopropylmethyl)-3,14 β-dihydroxy-4,5 α-epoxy-6β-[N-methyl-trans-3-(3-furyl) acrylamido] morphinan hydrochloride (intravenous use)	Treatment of uremic pruritus
Danish	(-)-17-(cyclopropylmethyl)-3,14 β-dihydroxy-4,5 α-epoxy-6β-[N-methyl-trans-3-(3-furyl) acrylamido] morphinan-hydrochlorid (intravenøs anvendelse)	Behandling af uræmisk pruritus
Dutch	(-)-17-(cyclopropylmethyl)-3,14 β-dihydroxy-4,5 α-epoxy-6β-[N-methyl-trans-3-(3-furyl) acrylamido] morfine hydrochloride (intraveneus gebruik)	Behandeling van uremische jeuk
Finnish	(-)-17-(syklopropyylimetyyli)-3,14 β-dihydroksi-4,5 α-epoksi-6β-[N-metyyli-trans-3-(3-furyyli) akryyliamido] morfinaani hydrokloridi (laskimoon)	Ureemisen kutinan hoito
French	chlorhydrate de (-)-17-(cyclopropylméthyl)-3,14 β-dihydroxy-4,5 α-époxy-6β-[N-méthyl-trans-3-(3-furyl) acrylamido] morphinane (voie intraveineuse)	Traitement du prurit urémique
German	(-)-17-(Cyclopropylmethyl)-3,14 β-dihydroxy-4,5 α-epoxy-6β-[N-methyl-trans-3-(3-furyl) acrylamido] morphinanhydrochlorid (intravenöse Anwendung)	Behandlung des uremischen Pruritus
Greek	(-)-17-(κυκλοπροπολυομεθυλο)-3,14 β-διυδροξυ-4,5 α-εποξυ-6β-[N-μεθυλο-trans-3-(3-φουρυλο) ακρυλαμιδο] υδροχλωρική μορφινάνη (Ενδοφλέβια χρήση)	Θεραπεία ουραιμικού κνησμού
Italian	(-)-17-(ciclopropilmetil)-3,14 β-diidrossido-4,5 α-epossi-6β-[N-metil-trans-3-(3-furfuril) acrilammide] idrocloruro di morfina (uso endovenoso)	Trattamento di prurito uremico
Portuguese	(-)-17-(ciclopropilmetil)-3,14 β-dihidroxi-4,5 α-epoxi-6β-[N-metil-trans-3-(3-furil) acrilamida] cloridrato de morfina (via intravenosa)	Tratamento do prurido urémico
Spanish	(-)-17-(ciclopropilmetilo)-3,14 β-dihidroxi-4,5 α-epoxi-6β-[N-metil-trans-3-(3-furil) acrilamida] clorhidrato de morfina (vía intravenosa)	Tratamiento del el prurito urémico
Swedish	(-)-17-(cyklopropylmetyl)-3,14-β-dihydroxi-4,5-α-epoxi-6-β-[N-metyl-trans-3-(3-furyl)-akrylamid]-morfinahydroklorid (intravenös användning)	Behandling av uremisk klåda

¹ At the time of designation