



COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

**PUBLIC SUMMARY OF
POSITIVE OPINION FOR ORPHAN DESIGNATION
OF**

**1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine, hydrochloride
for the treatment of narcolepsy**

On 10 July 2007, orphan designation (EU/3/07/459) was granted by the European Commission to Bioprojet, France, for 1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine, hydrochloride for the treatment of narcolepsy.

What is Narcolepsy?

Narcolepsy is characterised by excessive daytime sleepiness (patients have an irresistible urge to sleep, even in inappropriate times and places), and often have disturbed night sleep with very vivid dreams. In addition, some of the patients experience sudden episodes of severe muscle weakness (called cataplexy), potentially causing dangerous falls. Narcolepsy symptoms can be very severe and damage significantly both the private and professional life of the patients. Cataplexy can increase the risk of accidents, including car accidents. It can occur so suddenly that the patient does not have time to prepare and avoid falls or sudden attacks of sleep urge, for example.

What are the methods of treatment available?

Several products to treat the symptoms of narcolepsy were authorised in the Community at the time of submission of the application for orphan drug designation. 1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine may be of potential significant benefit in patients affected by narcolepsy. This 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, narcolepsy was considered to affect not more than 230,000 persons in the European Union.

How is this medicinal product expected to act?

The mechanism of action of 1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine in narcolepsy is not fully understood. It may involve regulation of neurotransmitters, which are chemical substances produced in the brain and used by brain cells to communicate between themselves, and this may improve the night sleep and indirectly decrease also the daytime symptoms.

What is the stage of development of this medicinal product?

The effects of 1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine were evaluated in experimental models.

* 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.

At the time of submission of the application for orphan designation, clinical trials in patients with narcolepsy were ongoing.

1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine was not authorised anywhere worldwide for narcolepsy or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 31 May 2007 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.

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

Language	Active Ingredient	Indication
English	1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine, hydrochloride	Treatment of narcolepsy
Bulgarian	1-{3-[3-(4-хлорфенил)пропокси]пропил}пиперидин хидрохлорид	Лечение на нарколепсия
Czech	1-{3-[3-(4-chlorofenyl)propoxy]propyl}piperidin, hydrochlorid	Léčba narkolepsie
Danish	1-{3-[3-(4-klorofenyl)propoxy]propyl}piperidin, hydroklorid	Behandling af narkolepsi
Dutch	1-{3-[3-(4-chloorfenyl)propoxy]propyl}piperidine, waterstofchloride	De behandeling van narcolepsie
Estonian	1-{3-[3-(4-klorofenüül)propoksü]propüül}piperidiinvesin ikkloriid	Narkolepsia ravi
Finnish	1-{3-[3-(4-kloorifenyyli)propoksi]propyyli}piperidiinihydrokloridi	Narkolepsian hoito
French	Chlorhydrate de 1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine	Traitement de la narcolepsie
German	1-{3-[3-(4-Chlorophenyl)Propoxy]Propyl}Piperidin, Hydrochlorid	Behandlung von Narkolepsie
Greek	1-{3-[3-(4-χλωροφαινυλο)προποξυ]προπυλο}πιπεριδίνη, υδροχλωρική	Θεραπευτική αγωγή για τη ναρκοληψία
Hungarian	1-{3-[3-(4-klorofenil)propoxi]propil}piperidin, hidroklorid	Narcolepsia kezelése
Italian	1-{3-[3-(4-clorofenil)propossi]propil}piperidina cloridrato	Trattamento della narcolessia
Latvian	1-{3-[3-(4-hlorofenil)propoksi]propil}piperidīns, hidrohlorīds	Narkolepsijas ārstēšanai
Lithuanian	1-{3-[3-(4-chlorofenil)propoksi](propil}piperidinas, hidrochloridas	Narkolepsijos gydymas
Maltese	1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine, hydrochloride	Kura tan-narkolessija

Polish	Chlorowodorek 1-{3-[3-(4-chlorofenylo)propoksy]propylo}piperydyny	Leczenie narkolepsji
Portuguese	1-{3-[3-(4-clorofenil)propoxi]propil}piperidina, cloridrato	Tratamento da narcolepsia
Romanian	Clorhidrat de 1-{3-[3-(4-clorofenil)propoxi]propil}piperidin,	Tratamentul narcolepsiei
Slovak	1-{3-[3-(4-chlórphenyl)propoxy]propyl}piperidíniumchlorid	Liečba narkolepsie
Slovenian	1-{3-[3-(4-klorofenil)propoksi]propil}piperidin hidroklorid	Zdravljenje narkolepsije
Spanish	1-{3-[3-(4-clorofenil)propoxi]propil}piperidina, hidrocioruro	Tratamiento de la narcolepsia
Swedish	1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidin, hydrochlorid	Behandling av narkolepsi
Norwegian	1-{3-[3-(4-klorfenyl)propoksy]propyl}piperidin, hydroklorid	Behandling av narkolepsi
Icelandic	1-{3-[3-(klórófenýl)própoxy]própýl}piperidín, hýdróklóríð	Meðferð drómasýki