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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Etilefrine for the treatment of low flow priapism

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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.	

On 13 November 2002, orphan designation (EU/3/02/122) was granted by the European Commission to Laboratoires SERB, France, for etilefrine for the treatment of low flow priapism.

What is low flow priapism?

Low flow priapism is a medical disorder in which there is persistent erection of the penis in the absence of sexual interest. Patients with low flow priapism usually present with a history of several hours of painful erection. It is believed that this condition is caused by obstruction to the normal drainage of blood from the erectile tissues. This obstruction causes buildup of poorly oxygenated blood. If the process continues for several days, abnormal thickening and scarring of the erectile tissue may develop, causing impotence. Low flow priapism is a serious and debilitating disease if it is not treated adequately and promptly.

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

At the time of designation, low flow priapism affected approximately 0.11 in 10,000 people in the European Union (EU). This was equivalent to a total of around 4,200 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).

[*]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.
At the time of designation, this represented a population of 380,600,000 (Eurostat 2002).

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What treatments are available?

There are no medicinal products that have been authorised for the treatment of priapism in the Community. Treatments which are currently used include medical treatment, for instance with medications consisting of certain adrenalin-like substances (alpha adrenergic agonists) or, if necessary, surgical procedures.

How is this medicine expected to work?

Etilefrine is a substance that stimulates the sympathetic nervous system. This system is involved in regulating several processes such as pulse, blood pressure, and the tone of smooth muscle. The erection of the penis depends on the relaxation of the smooth muscle of the two columns of erectile tissue at either side of the penis (corpora cavernosa). The relaxation causes widening of the blood vessels and the tissue is filled with blood causing the erection. The injection of etilefrine inside the *corpora cavernosa* leads to a decrease in the blood supply to the penis and may also increase the drainage of blood from the erectile tissues. It is expected that this will produce a gradual reduction in the erection.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation no clinical trials in patients with low flow priapism had been initiated.

Etilefrine had not been marketed anywhere worldwide for low flow priapism 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 9 October 2002 recommending the granting of this designation.

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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 languages[1], Norwegian and Icelandic

Language	Active Ingredient	Indication
English	Etilefrin	Treatment of low flow priapism
Danish	Etilefrin	Behandling af lavt flow priapisme
Dutch	Etilefrin	Behandeling van low flow priapisme
Finnish	Etilefriini	Low flow priapismin hoito
French	Étiléfrine	Traitement du priapisme à bas débit sanguin.
German	Etilefrin	Behandlung des Low-Fow Priapismus
Greek	Etilefrin	Θεραπεία χαμηλής ροής priαπισμού
Italian	Etilefrina	Trattamento del priapismo a basso flusso
Portuguese	Etilefrina	Tratamento de priapismo de baixo fluxo
Spanish	Etilefrina	Tratamiento del priapismo de bajo flujo
Swedish	Etilefrin	Behandling av priapism med lågt flöde

[1] At the time of designation