



EUROPEAN MEDICINES AGENCY
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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Abarelix for the treatment of low-flow priapism

First publication	15 October 2010
Rev.1: withdrawal from the Community Register	9 November 2012
Rev.2: administrative update	14 October 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Please note that this product was withdrawn from the Community Register of designated orphan medicinal products in October 2012 on request of the sponsor.

On 20 September 2010, orphan designation (EU/3/10/771) was granted by the European Commission to Speciality European Pharma Ltd, United Kingdom, for abarelix for the treatment of low-flow priapism.

What is low-flow priapism?

Priapism is the prolonged and often painful erection of the penis occurring without sexual stimulation. In low-flow priapism, the prolonged erections are caused by a blockage of the blood flow out of the penis. This leads to the build up of blood that is low in oxygen and, as a consequence, the tissues in the penis may not receive enough oxygen. The erections can last for several hours and are usually considered a medical emergency. Low-flow priapism may be caused by a medicine the patient may be taking or a disease of the blood such as sickle cell disease.

Low-flow priapism is a debilitating disease because it can lead to erectile dysfunction (inability to get or keep an erection) and permanent damage to the penis.



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

At the time of designation, low-flow priapism affected less than 0.5 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 25,000 people*, and is below the threshold 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?

At the time of submission of the application for orphan drug designation, no satisfactory methods were authorised for low-flow priapism in the EU. Treatments used included surgery, medicines known as 'alpha-agonists' that help to widen the veins and treatments for the underlying cause of the priapism if it is known.

How is this medicine expected to work?

The hormone testosterone is involved in causing erections. Abarelix is a gonadotrophin-releasing hormone antagonist, which means that it blocks the effects of a natural hormone called gonadotrophin-releasing hormone (GnRH). GnRH stimulates the testes to produce testosterone. By blocking the actions of GnRH, abarelix is expected to reduce the amount of testosterone in the body, helping to treat episodes of priapism or to prevent them from happening again.

What is the stage of development of this medicine?

The effects of abarelix have been evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials with abarelix in patients with priapism had been started.

At the time of submission, the medicine was authorised in Germany for suppressing testosterone levels in patients with advanced or metastatic hormone-dependent prostate cancer.

At the time of submission, abarelix was not authorised anywhere in the EU for low-flow priapism or designated as an orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 2 June 2010 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 27), Norway, Iceland and Liechtenstein. At the time of designation, this represented a population of 506,300,000 (Eurostat 2010).

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	Abarelix	Treatment of low-flow priapism
Bulgarian	Абареликс	Лечение на прекъсващ ишемичен приапизъм
Czech	Abarelix	Léčba nízce průtokového priapismu
Danish	Abarelix	Behandling af lavt flow priapisme
Dutch	Abarelix	Behandeling van low flow priapisme
Estonian	Abareliks	Low flow priapismi ravi
Finnish	Abareliksi	Vähävirtauksisen priapismin hoito
French	Abarélix	Traitement du priapisme à bas débit sanguin.
German	Abarelix	Behandlung des Low-Fow Priapismus
Greek	Αβαρελιξη (abarelix)	Θεραπεία χαμηλής ροής πριαπισμού
Hungarian	Abarelix	Alacsony keringésű priapizmus kezelése
Italian	Abarelix	Trattamento del priapismo a basso flusso
Latvian	Abareliks	Lēnas plūsmas priapisma ārstēšana
Lithuanian	Abareliksas	Išeminio priapizmo (ilgalaikės skausmingos erekcijos) gydymas
Maltese	Abarelix	Kura ta' priapizmu bi fluss baxx
Polish	Abareliks	Leczenie priapizmu niskoprzepływowego (niedokrwiennego)
Portuguese	Abarelix	Tratamento de priapismo de baixo fluxo
Romanian	Abarelix	Tratamentul priapismului cu debit scăzut
Slovak	Abarelix	Liečba nízkoprietokového priapizmu
Slovenian	Abareliks	Zdravljenje priapizma zaradi zmanjšane prekrvitve
Spanish	Abarelix	Tratamiento del priapismo de bajo flujo
Swedish	Abarelix	Behandling av priapism med lågt flöde
Norwegian	Abareliks	Behandling av low flow priapisme
Icelandic	Abarelix	Meðferð við láglóðflæðis standpínu

¹ At the time of designation