

22 March 2011
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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

α -1-acid glycoprotein for the treatment of cocaine poisoning

Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in June 2010 on request of the Sponsor.

On 2 October 2003, orphan designation (EU/3/03/164) was granted by the European Commission to Bio Products Laboratory, United Kingdom, for α -1-acid glycoprotein for the treatment of cocaine poisoning.

What is cocaine poisoning?

Cocaine is a substance that is widely misused because of its euphoric effect, but it can be very harmful and it can cause illness or death, so called poisoning. Accidental poisoning or poisoning for the purpose of committing suicide with cocaine can be life threatening due to serious impairment of the heart, the lungs and the brain function.

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

At the time of designation, cocaine poisoning affected approximately 0.1 in 10,000 people in the European Union (EU)*. This is equivalent to a total of around 3,800 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?

Patients with cocaine poisoning are treated with the general measures of treatment of poisonings. These include emptying of the stomach and using active charcoal (a type of carbon) administered into the stomach, to prevent further uptake into the body. Medicines are administered to correct the blood

*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. This estimate is based on available information and calculations presented by the sponsor at the time of the application.

if it becomes too acid and in some cases there is need to administer medicines to correct any heart problem. Help with breathing is also used if necessary.

How is this medicine expected to work?

Alpha-1 acid glycoprotein is a protein naturally occurring in the blood, which binds several substances including cocaine. Administration of additional amounts of this protein in cocaine poisoning is expected to increase the binding of the ingested substances, and this should reduce their toxic effects.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, clinical trials were ongoing.

Alpha-1 acid glycoprotein was not marketed anywhere worldwide for cocaine poisoning, at the time of submission. The sponsor had not applied for orphan designation outside the European Union.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 30 July 2003 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	α -1-acid glycoprotein	Treatment of cocaine poisoning
Danish	α -1-syre glykoprotein	Behandling af overdosering med kokain
Dutch	α -1-zuurglycoproteïne	Behandeling van cocaine vergiftiging
Finnish	Hapan α -1-glykoproteiini	Kokaiinimyrkytyksen hoito
French	α -1 glycoprotéine acide	Traitement des intoxications à la cocaïne
German	α 1 saures Glycoprotein	Behandlung der Kokainintoxikation
Greek	α -1 όξινη γλυκοπρωτεΐνη	Θεραπεία δηλητηρίασης από κοκαΐνη.
Italian	Glicoproteina acida α -1	Trattamento dell'intossicazione da cocaina
Portuguese	Glicoproteína ácida α -1	Tratamento da intoxicação por cocaína
Spanish	Glicoproteína ácida α -1	Tratamiento de la intoxicación por cocaína
Swedish	α -1-syra glykoprotein	Behandling av kokainförgiftning

¹ At the time of designation