



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

α -1-acid glycoprotein for the treatment of tricyclic antidepressants poisoning

Please note that this product was withdrawn from the Community Register of designated orphan medicinal products in April 2010 on request of the sponsor.

On 20 March 2003, orphan designation (EU/3/03/138) was granted by the European Commission to Bio Products Laboratory, United Kingdom, for α -1-acid glycoprotein for the treatment of tricyclic antidepressants poisoning.

What is tricyclic antidepressants poisoning?

Tricyclic antidepressants are a group of substances that are widely used in the treatment of depression, which is a disease of the mood. Accidental poisoning or poisoning for the purpose of committing suicide with these substances can be life threatening due to serious damage to the heart, the lung and the brain.

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

At the time of designation, tricyclic antidepressants poisoning affected approximately 1.5 in 10,000 people in the European Union (EU)*. This is equivalent to a total of around 57,000 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?

Patients with tricyclic antidepressants 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) to prevent further uptake into the body, medicines to correct the blood if it becomes too acid, help with breathing if necessary. In some cases medicines to correct any heart problems are used, and in some

*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.



cases the substance physostigmine is used to counteract some of the effects of poisoning to the organism.

How is this medicine expected to work?

Alpha-1 acid glycoprotein is a protein naturally occurring in the blood, which binds several substances including tricyclic antidepressants. Administration of additional amounts of protein in tricyclic antidepressants poisoning is expected to increase binding of the ingested substances, and this should reduce the 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 tricyclic antidepressants 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 7 February 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 European Union) 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

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