



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

**PUBLIC SUMMARY OF
NEGATIVE OPINION FOR ORPHAN DESIGNATION
OF
sudismase
for the treatment of active phase of Peyronie's disease**

On 16 November 2004, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of sudismase for the treatment of active phase of Peyronie's disease. A negative decision was granted by the European Commission on 16 June 2005.

The sponsor applied for orphan designation on the basis of the chronically debilitating nature and rarity of the condition, as well as an assumption of potential benefit despite currently available methods of treatment.

The negative opinion is based on the following elements:

- For the purposes of designation as orphan medicinal product, justification has not been provided for limiting the condition to the active phase of Peyronie's disease*;
- It had not been established that active phase of Peyronie's disease affects not more than 5 in 10,000 persons in the Community at the time the application was made;

Requests for designation as orphan medicinal products are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials, and subsequently the possibility of obtaining a marketing authorisation if quality, safety and efficacy are demonstrated.

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*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.

Patients' association contact point:

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