

6 January 2017
EMA/751496/2016
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

3-(3-Methanesulfonyl-phenyl)-1-propyl-piperidine hydrochloride for the treatment of narcolepsy

On 13 July 2016, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for 3-(3-methanesulfonyl-phenyl)-1-propyl-piperidine hydrochloride for the treatment of narcolepsy. A negative decision was issued by the European Commission on 2 December 2016.

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

The negative opinion was based on the following reasons:

- the data submitted were not sufficient to show that the medicine, either on its own or in a proposed combination with methylphenidate, may be effective at treating narcolepsy;
- the sponsor failed to show that narcolepsy affects not more than 5 in 10,000 people in the EU;
- the data submitted were not sufficient to show that the medicine could be of significant benefit to patients in terms of its effectiveness and safety compared with other treatments or its contribution to patient care.

Requests for designation as an orphan medicinal product are made for investigational products. Absence of orphan designation does not preclude the development of this product, including its use in clinical trials. A marketing authorisation can still be obtained if quality, safety and efficacy are demonstrated.

For more information:

Sponsor's contact details:

Contact details of the current sponsor for this orphan designation can be found on EMA website, on the medicine's [rare disease designations page](#).

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.