30 September 2015
EMA/COMP/504453/2015
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Nalbuphine hydrochloride for the treatment of uraemic pruritus

On 27 February 2015, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for nalbuphine hydrochloride for the treatment of uraemic pruritus (itching associated with chronic kidney disease). A negative decision was issued by the European Commission on 3 July 2015.

The sponsor applied for orphan designation on the basis of the seriousness and the rarity of the condition.

The negative opinion was based on the following reason:

- the sponsor failed to establish that uraemic pruritus is a distinct, recognisable medical entity with signs and symptoms that can be distinguished from pruritus caused by other conditions.

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:

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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.