



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 May 2017
EMA/211260/2017
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

20% intravenous fat emulsion consisting of 20% soybean oil, 1.2% egg yolk phospholipids, 2.25% glycerin, and water for injection for the treatment of poisoning by local anaesthetics

On 3 April 2017, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on the orphan designation application for 20% intravenous fat emulsion consisting of 20% soybean oil, 1.2% egg yolk phospholipids, 2.25% glycerin, and water for injection for the treatment of poisoning by local anaesthetics. A negative decision was issued by the European Commission on 20 April 2017.

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 reasons:

- the sponsor failed to establish that poisoning by local anaesthetics is a distinct recognisable medical entity in terms of its effects on the body;
- the sponsor has not established that the condition affected no more than 5 in 10,000 persons in the European Union at the time of submission.

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.