EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2015
EMA/CHMP/471000/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion [1] (initial authorisation)

Zalviso

sufentanil

On 23 July 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zalviso, intended for the treatment of post-operative pain. The applicant for this medicinal product is Grunenthal GmbH.

Zalviso will be available as 15 µg sublingual tablet. The active substance of Zalviso is sufentanil, an opioid which produces analgesia via activation of µ-opioid receptors primarily within the central nervous system.

The benefits with Zalviso are its ability to reduce post-operative pain. The most common side effects are nausea, vomiting, pyrexia and headache.

Zalviso is a hybrid of Sufenta, which has been authorised in the Netherlands since 1978 as an anaesthetic-analgesic.

The full indication is: "Zalviso is indicated for the management of acute moderate to severe post-operative pain in adult patients."

It is proposed that Zalviso be prescribed by physicians experienced in the management of opioid therapy. Zalviso is to be administered in a hospital setting only.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact