EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2018
EMA/CHMP/199029/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dzuveo

sufentanil

On 26 April 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dzuveo, intended for the treatment of pain. The applicant for this medicinal product is FGK Representative Service GmbH.

Dzuveo will be available as 30-microgram sublingual tablets. The active substance of Dzuveo is sufentanil, an opioid (ATC code: N01AH03) which produces analgesia by activating μ-opioid receptors primarily within the central nervous system.

The benefits with Dzuveo are its ability to reduce pain. The most common side effects are nausea, vomiting and pyrexia.

Dzuveo is a hybrid medicine[2] of Sufenta which has been authorised in the EU since 1978. Dzuveo contains the same active substance as Sufenta, but is given in a different way.

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

Dzuveo should only be administered by healthcare professionals who are experienced in the management of opioid therapy.

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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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