European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 April 2009
Doc. Ref. EMEA/CHMP/65031/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
INSTANYL

International Nonproprietary Name (INN): ***fentanyl***

On 23 April 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Instanyl, 0.5 mg/ml, 1.0 mg/ml, 2.0 mg/ml, nasal spray, solution, intended for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain. The applicant for this medicinal product is Nycomed Danmark ApS.

The active substance of Instanyl is fentanyl citrate, a phenylpiperidine derivative medicinal product (N02AB03) acting on the opioid receptor.

The benefits with Instanyl are its nasal route of administration, which avoids first-pass metabolism of the active substance and provides quick onset of analgesic action. The most common side effects are, as for other fentanyl preparations, somnolence, dizziness, headache, nausea and vomiting.

A pharmacovigilance plan for Instanyl, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Instanyl is indicated for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain."

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.
The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Instanyl and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 8613
E-mail: mail@emea.europa.eu http://www.emea.europa.eu
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