

Product Update:

fentanyl 50, 100, 200 microgram single dose nasal spray (Instanyl®)
(No:750/11)

Nycomed UK Ltd

09 December 2011

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

fentanyl single dose nasal spray (Instanyl®) is accepted for restricted use in NHS Scotland.

Indication under review: 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.

Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30 mg oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

SMC restriction: to patients who are unsuitable for other short-acting oral opioids (e.g. oral morphine) as an alternative to other buccal and sublingual fentanyl preparations. It should be noted that the doses of fentanyl nasal spray are significantly lower than doses of fentanyl given by other routes of administration for this indication.

In a pharmacokinetic study in healthy volunteers, this single dose fentanyl nasal spray presentation was shown to be bioequivalent to the multi-dose nasal spray presentation and is available at equivalent cost per dose.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the

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exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 17 October 2011.

**Chairman
Scottish Medicines Consortium**