Scottish Medicines Consortium

Providing advice about the status of all newly licensed medicines



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Product Update:

bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) (No: 761/12)

Goldshield Pharmaceuticals Ltd.

13 January 2012 (Issued 10 February 2012)

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

bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) is accepted for use in NHS Scotland.

Indication under review: epidural analgesia to relieve pain during labour and to control post operative pain.

For patients in whom the combination of bupivacaine and fentanyl is an appropriate choice of therapy, Bufyl® provides two fixed-dose, pre-mixed preparations.

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 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 16 November 2011.

Chairman
Scottish Medicines Consortium