Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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Product Update:

buprenorphine 2mg, 8mg oral lyophilisate (Espranor®)

SMC No (1245/17)

Martindale Pharma

05 May 2017

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

buprenorphine oral lyophilisate (Espranor®) is accepted for restricted use within NHS Scotland.

Indication under review: Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction.

SMC restriction: to patients in whom methadone is not suitable.

In patients who require supervised consumption of buprenorphine, the oral lyophilisate formulation has the advantage of a faster dissolution time compared to other available buprenorphine preparations.

Prescribers should be aware that buprenorphine preparations are not interchangeable.

Generic buprenorphine sublingual tablets are available at lower cost.

This SMC advice takes account of the benefit of a Patient Access Scheme (PAS) that improves the cost effectiveness of buprenorphine oral lyophilisate. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.

Published 12 June 2017

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.

A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a drug and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG, established under the auspices of NHS National Services Scotland reviews and advises NHS Scotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHS Scotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

This assessment is based on data submitted by the applicant company up to and including 14 April 2017.

Chairman
Scottish Medicines Consortium