

## Product Update:

### ondansetron 4mg, 8mg orodispersible films (Setofilm<sup>®</sup>) (SMC No. 912/13) Norgine

04 October 2013

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

**ondansetron orodispersible films (Setofilm<sup>®</sup>)** are accepted for restricted use within NHS Scotland.

**Indication under review:**

In adults:

- Prophylaxis of acute nausea and vomiting induced by moderately emetogenic chemotherapy.
- Prophylaxis and treatment of delayed nausea and vomiting induced by moderately to highly emetogenic chemotherapy.
- Prophylaxis and treatment of acute and delayed nausea and vomiting induced by highly emetogenic radiotherapy.
- Prophylaxis and treatment of post-operative nausea and vomiting (PONV).

In paediatric populations:

- Management of chemotherapy-induced nausea and vomiting in children aged  $\geq 6$  months.
- Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged  $\geq 4$  years.

**SMC restriction:** ondansetron orodispersible films are restricted to use in patients with an enhanced risk of aspiration or who experience difficulties in swallowing.

Generic preparations of ondansetron are available at a lower cost than the proprietary products.

**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 15 August 2013.*

**Chairman  
Scottish Medicines Consortium**