



UK MEDIA RELEASE

SCOTTISH MEDICINES CONSORTIUM ACCEPTS COST-EFFECTIVENESS OF SETOFILM[®] (ORODISPERSIBLE FILM ONDANSETRON) INNOVATIVE FORMULATION DISSOLVES IN SECONDS

London. Monday 11th November, 2013. Norgine announced today that the Scottish Medicines Consortium (SMC) has accepted the restricted use of its medicine SETOFILM[®] orodispersible films (ondansetron) within NHS Scotland following an abbreviated submission from the company. SETOFILM[®] orodispersible films are licensed for the prevention and treatment of Chemotherapy-Induced Nausea and Vomiting (“CINV”) in adults, as well as patients aged 6 months or above, Radiotherapy-Induced Nausea and Vomiting (“RINV”) in adults, and the prevention and treatment of Post-Operative Nausea and Vomiting (“PONV”) in adults and patients aged 4 years or above.^{i,ii}

SETOFILM[®] is the first prescription-only medicine developed as an orodispersible film (ODF) formulation to be registered in Europe. The product is available in 4mg and 8mg doses. Once placed on the tongue, it dissolves in a few seconds and is swallowed with saliva without the need for water.ⁱⁱⁱ The innovative ODF form may reduce the patient pill burden and enable patients to take their medication virtually anywhere.ⁱⁱⁱ

The SMC’s decision follows on from the All Wales Medicines Strategy Group’s decision that SETOFILM[®] meets its exclusion criteria^{iv} and NICE’s decision not to undertake an assessment at this time. In Europe, SETOFILM[®] is already available for healthcare professionals to prescribe in accordance with local guidance.

Bob Cuffe, General Manager, UK & Ireland, Norgine, said: “We are delighted that the SMC recognises the value of SETOFILM[®], and its role in helping both adults and children who are suffering from debilitating side-effects especially following chemotherapy treatment and other very serious conditions.”

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Notes to editors

The SMCⁱ (SMC No. 912/13) announced its final decision as follows:

ADVICE: following an abbreviated submission

ondansetron orodispersible films (Setofilm[®]) 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 ≥ 6 months.
- Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged ≥ 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.

About Norgine

Norgine is a successful, independent European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2012, Norgine's net product sales were c€250 million and the company employs over 1,000 people.

Norgine's focus is the development and marketing of pharmaceutical products that address significant unmet clinical needs in therapeutic areas such as gastroenterology, hepatology and critical and supportive care.

Norgine owns a manufacturing and development site in Hengoes, UK and a manufacturing site in Dreux, France.

For more information, please visit www.norgine.com.

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http://www.scottishmedicines.org.uk/SMC_Advice/Advice/912_13_ondansetron_Setofilm_ABBREVIATED/ondansetron_Setofilm_Abbreviated Published online on 11th November 2013

ii SETOFILM® Summary of Product Characteristics. Norgine, 2013, available online at <http://www.medicines.org.uk/emc/medicine/28020/SPC/Setofilm+4+mg+Orodispersible+Films/>

iii Reiner V, Giarratana N, Monti NC, et al. Rapidfilm®: An innovative pharmaceutical form designed to improve patient compliance. *Int J Pharmaceutics* 2010;393;55-60.

iv <http://www.awmsg.org/awmsgonline/app/appraisalinfo/2214>