IRISH MEDICINES BOARD

Notice Information: - Warning
19 February 2009

Part 1. Product Information

a)	Title:	Raptiva - Suspension of Marketing
b)	Product Name/Type:	Raptiva (efalizumab) 100 mg/ml powder and solvent for solution for injection
c)	Active Substance:	Efalizumab
d)	Product Classification:	Selective immunosuppressive medicine (monoclonal antibody)
e)	Prescription Required:	Yes

Part 2. Problem/Issue

a)	Problem/Issue:	IMMEDIATE SUSPENSION OF THE MARKETING OF RAPTIVA The Irish Medicines Board [IMB] today announced the suspension of the marketing of Raptiva 100 mg/ml powder and solvent for solution for injection in Ireland, with immediate effect, based on a recommendation by the European Medicines Agency (EMEA). Raptiva is a prescription only medicine containing the active substance efalizumab, and is used in the treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, who have a contraindication to, or who are intolerant to other systemic therapies. It has been authorised in the EU since 2004. The EMEA's Committee for Medicinal Products for Human Use (CHMP) has concluded, following reports of serious side effects, including three confirmed cases of 'progressive multifocal leukoencephalopathy' (PML) in patients who had taken Raptiva for more than three years, that the benefits of Raptiva no longer outweigh its risks and that the marketing authorisation should be suspended across the European Union (EU). PML is a rare brain infection that can lead to severe disability or can be fatal. To date, the IMB has not received any reports of PML associated with use of Raptiva in Ireland.

Part 3. Action to be taken

a) Action to be taken:

Advice to patients/consumers:

- Do not stop taking Raptiva abruptly.

- Make an appointment to see your dermatologist for a review of your condition and further advice regarding alternative treatments.

Advice to Healthcare Professionals:

- No new patients should be started on Raptiva.

- Existing supplies of Raptiva in pharmacies are not being immediately recalled at this time in order to ensure that treatment with Raptiva is not abruptly halted. However, Raptiva will shortly become unavailable in Ireland.

- Patients currently taking Raptiva should be reviewed to assess the most appropriate alternative treatment options. Management of patients discontinuing Raptiva requires observation.

- For patients presenting with a prescription for Raptiva, the pharmacist should check with the patient's physician to confirm that the physician is aware of the suspension of the marketing of this product and the requirement for management of discontinuation of Raptiva therapy in the short-term.

- Physicians should ensure that patients who have been treated with Raptiva are closely monitored for neurological symptoms and signs of infection.

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	The IMB is working with the company to ensure healthcare professionals are informed of this issue.

Part 4. Enquiries

a) All enquiries should be made to:	The Press Release is available for download. Further information, including a Questions and Answers document, is available from the EMEA Website http://www.emea.europa.eu/home.htm Patients and healthcare professionals who have any queries can contact the IMB on 01-6764971 Media Queries: Siobhan Molloy / Angie Grant (Weber Shandwick) Tel: (01) 676 01 68 or 086 817 50 66 / 086 377 2791

Part 5. Keywords

a) Keywords:	Raptiva efalizumab