Dear Sir/Madam

RELISTOR® ▼ - Important information for healthcare professionals involved with palliative care

The European Commission approved Relistor *(methylnaltrexone bromide)* on 2nd July 2008, for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. Relistor is administered subcutaneously.

At the request of the Regulatory Authorities, Wyeth wishes to make you aware of two important features of this new product:

1. Relistor is licensed for use in adult advanced illness patients receiving palliative care who are suffering from constipation related to opioid therapy. It is used when the response to usual laxative treatment has not been sufficient. Safety and efficacy of the product have only been tested in patients with advanced illness receiving palliative care (e.g. cancer, HIV/AIDS, COPD).

2. Guidance is available for appropriate use of Relistor by patients themselves or by their immediate caregivers (in case these are non-healthcare professionals). To avoid overdosing, patients or caregivers should be made aware that one vial does not always contain the appropriate single dose. For patients weighing 38-61 kg, only 8 mg (0.4 ml) of the 12 mg (0.6 ml) dose contained in the vial should be used. The remaining volume should be discarded. For patients weighing 62-114 kg, the recommended dose is 12 mg (0.6 ml).

Relistor presentations available:
- Single vial
- 7-pack convenience kit (each pack contains one vial of Relistor, a single-use syringe with an attached retractable needle with appropriate dose markings, and two alcohol swabs)
- Each pack contains a Patient Information Leaflet (PIL)

Summary of Product Characteristics

The full Summary of Product Characteristics is available at www.medicines.org.uk.

The Patient Information Leaflet enclosed gives step-by-step instructions on how to prepare and administer an injection of Relistor. Please share these instructions with patients or caregivers when explaining how to self-administer/administer.

All individuals within your multi-disciplinary team involved in the care of these patients should be made aware of the availability of these instructions. A guide entitled "How to Administer your RELISTOR Injection" is also available and can be obtained by contacting the Wyeth Medical Information Department, either by phone on 0845 367 0098 or by email to ukmedinfo@wyeth.com.

Healthcare professionals should report any adverse events suspected to be associated with the use of Relistor to the Medicines and Healthcare products Regulatory Agency (MHRA) using a yellow card available directly from the MHRA, CHM Freepost, London SW8 5BR, or electronically via the website www.yellowcard.gov.uk. Adverse events should also be reported to Wyeth Pharmacovigilance UK by phone on 0845 367 0115, by fax on 0845 367 0600 or by e-mail to watwadr@wyeth.com.

For further information visit www.relistor.co.uk or contact our Medical Information Department by phone on 0845 367 0098, or by email to ukmedinfo@wyeth.com.

Yours faithfully

Dr Vignesh Rajah
Medical Director
Wyeth UK

® Registered Trade Mark

Enclosed: Patient Information Leaflet