Wyeth updates safety information for venlafaxine and moroctocog alfa

Wyeth Canada has issued 'Dear Health Care Professional' letters regarding important safety information for venlafaxine and moroctocog alfa.

Following discussions with Health Canada, Wyeth has distributed the same information regarding the use of venlafaxine ['Effexor', 'Effexor XR'] in children and adolescents that was contained in a letter issued in the US in August 2003.[1,2] The information reflected safety information from clinical trials in paediatric patients in which there were increased reports of hostility and suicide-related adverse events among patients receiving venlafaxine compared with those receiving placebo.* Furthermore, efficacy of venlafaxine for the treatment of major depressive disorder or generalised anxiety was not established in these trials. Wyeth also notes that venlafaxine was not and is not now recommended for use in paediatric patients.

Wyeth has also notified healthcare professionals of information received from voluntary postmarketing reports of adverse events associated with moroctocog alfa ['ReFacto'], licensed in Canada for the control and prevention of haemorrhagic episodes in patients with haemophilia A.[3] Reports of lack of effect have been received during clinical trials and in the postmarketing setting. Lack of effect and/or low factor VIII recovery has been reported in patients with inhibitors but also in patients with no evidence of inhibitors. The lack of effect has been described as bleeding into target or new joints, other bleeding or a subjective feeling by the patient of new-onset bleeding. As of 12 Apr 2003, Wyeth had received 85 postmarketing reports (representing 81 patients) of lack of effect and/or low recovery associated with moroctocog alfa in which concurrent inhibitor data was negative or not provided; the company estimates approximately 5800 patients have used the agent in that time. Wyeth advises that doses of moroctocog alfa must be individually titrated in order to ensure an adequate therapeutic response, and the product monograph has been updated to include the new information.

* For more information regarding the adverse events reported in these studies see Inpharma 1406: 21, 27 Sep 2003; 800863954.

1. Wyeth Pharmaceuticals. Upate to the prescribing information for Effexor (Rm) (venlafaxine HCl) Tablets and Effexor (Rm) XR (venlafaxine HCl) Extended-Release Capsules to reflect important safety information on the use of venlafaxine in children and adolescents. Internet Document : [2 pages], 10 Sep 2003. Available from: URL: http://www.hc-sc.gc.ca.
2. Wyeth Pharmaceuticals. Important safety information: regarding the use of Effexor (Rm) (venlafaxine HCl) Tablets and Effexor (Rm) XR (venlafaxine CIl) Capsules in children and adolescents. Internet Document : [2 pages], 10 Sep 2003. Available from: URL: http://www.hc-sc.gc.ca.
3. Wyeth Canada. Important safety information about ReFacto (Rm) (moroctocog alfa), Antihemophilic Factor (Recombinant) [BDDrFVIII]). Internet Document : [3 pages], 15 Sep 2003. Available from: URL: http://www.hc-sc.gc.ca.

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