

# Notice Information: - 3rd Party Publications 21 December 2012

#### Part 1. Product Information

Title:	European Medicines Agency (EMA) announces a review of Tredaptive, Pelzont and Trevaclyn
Product Name/Type:	Tredaptive, Pelzont, Trevaclyn
Active Substance:	

### Part 2. Problem/Issue

a) Problem/Issue:

The EMA has commenced a review of the safety and efficacy of Tredaptive, Pelzont and Trevaclyn, medicines which are used to treat adults with dyslipidaemia (abnormally high levels of fat in the blood), particularly 'combined mixed dyslipidaemia' and 'primary hypercholesterolaemia'. The review was triggered after the Agency was informed by the pharmaceutical company Merck, Sharp and Dohme of the preliminary results of a large, long-term study comparing the clinical effects of adding these medicines to statins (standard medicines used to reduce cholesterol) with statin treatment alone. The study raises questions about the efficacy of the medicine when added to statins, as this did not reduce the risk of major vascular events (serious problems with the heart and blood vessels, including heart attack and stroke) compared with statin therapy alone.

#### Part 3. Action to be taken

a) Action to be taken:

Pending the outcome of this review (expected in January 2013), the EMA recommends that no new patients should be started on treatment with these medicines. Patients currently using Tredaptive, Pelzont or Trevaclyn should not stop their treatment. Patients who have any questions should speak to their doctor at their next appointment.

Healthcare professionals in the European Union (EU) will receive a letter in the next few days outlining the updated information on the use of these medicines.

For full EMA statement please refer to link below.

European Medicines Agency - press release

Tredaptive (nicotinic acid/laropiprant) - Letter to Healthcare Professionals

Irish Medicines Board communication on PRAC recommendation on Tredaptive

## Part 4. Keywords

a) Keywords:

Tredaptive Pelzont Trevaclyn