

To:
Head of Paediatric Medicines
European Medicines Agency
7 Westferry Circus
London E14 4HB
United Kingdom
paediatrics@ema.europa.eu

Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): nicotinic acid / laropiprant
Invented name: TREDAPTIVE

Latest Decision number(s): 1) P/0262/2012 2) P/45/2007 3) P/46/2007 4)

Corresponding PIP number(s): 1) EMEA-000063-PIP01-07-M01 2) EMEA-000251-PIP01-08 3)
EMEA-000252-PIP01-08 4)

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Treatment of dyslipidaemia
Prevention of major vascular and major coronary events

- ☒ has been discontinued
☐ has been suspended/put on long-term hold (with possible re-start at a later time)

for the following reason(s): *(tick all that apply)*

- ☐ (possible) lack of efficacy in adults
☐ (possible) lack of efficacy in children
☐ (possible) unsatisfactory safety profile in adults
☐ (possible) unsatisfactory safety profile in children
☐ commercial reasons (please specify:)
☐ manufacturing / quality problems
☒ other regulatory action (please specify: MA withdrawn as endorsed by the European Commission on April 10, 2013) (e.g. suspension, revocation of M.A.)
☐ other reason (please specify:)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

The HPS2-THRIVE study did not meet its primary endpoint of reduction of major vascular events which included the combination of coronary deaths, non-fatal heart attacks, strokes or revascularizations. Also in this study, there was a statistically significant increase in the incidence of some types of non-fatal serious adverse events in the group that received TREDAPTIVE and statin compared to the group that received statin without TREDAPTIVE.

Name and signature of the PIP contact point: Emilie Niedercorn

Date: 3 October 2013

Contact for inquiries from interested parties: stef.schutte@merck.com

Telephone: +31 412 663179

Email: +31 412 662571