

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): Tazarotene
Invented name:

Latest Decision number(s): 1) P/0250/2012 2) P/109/2011 3) P/3/2011 4) P/

Corresponding PIP number(s): 1) EMEA-000510-PIP02-10-M02 2) EMEA-000510-PIP02-10-M01 3) EMEA-000510-PIP02-10 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Treatment of lamellar ichthyosis

- 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:) *(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:

Inconclusive results of the primary efficacy parameter of the phase III study

Name and signature of the PIP contact point: signature on file

Date: 23/01/2015

Contact for inquiries from interested parties: Orfagen

Telephone: +33 534 506 457

Email: info@orfagen.com