

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): bisoctrizole, titanium dioxide
Invented name:

Latest Decision number(s): 1) P/90/2010 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000585-PIP01-09 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Solar urticaria

- ☒ 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:

Active substance status issue : GMP compliance

Name and signature of the PIP contact point: Agnès CANTONE

Date: 12/07/2013

Contact for inquiries from interested parties: Gea SPIERINGS

Telephone: +33 534 506 458

Email: gea.spierings@orfagen.com