

NOVAGALI P H A R M A

O/ REF: AR-08-081-SEF

Dr Eric Abadie
European Medicines Agency
7 Westferry Circus, Canary Wharf
London, E14 4HB
United Kingdom

Evry, 14 November 2008

Subject : Withdrawal of Vekacia (Ciclosporin), 0,05%, eye drops
EMEA/H/C/904

Dear Dr Abadie,

I would like to inform you that, at this point of time, Novagali has taken the decision to withdraw the application for Marketing Authorisation of Vekacia (Ciclosporin), 0,05%, eye drops, which was intended to be used for the treatment of vernal keratoconjunctivitis (VKC).

This withdrawal is based on the following reason:

The CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance of Vekacia at this point of time.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

I agree for this letter to be published on the EMEA website.

Yours sincerely,

Bâtiment Genavenir IV - 1, Rue Pierre Fontaine - 91058 Evry cedex/ France
Phone : 33 (0) 1 69 87 40 20 - Fax : 33 (0) 1 69 87 40 30

www.novagali.com

Société anonyme à Directeur et Conseil de Surveillance au capital de 508 790,56€ - 432 584 225 RCS EVRY
Ape : 7211Z - Siret : 432 584 225 000 28 - TVA : FR 66 432 584 225