

Sun Pharmaceutical Industries Europe BV

Polarisavenue 87
2132 JH Hoofddorp - The Netherlands
Tel: +31 (0)23 568 55 01
Fax: +31 (0)23 568 55 05



Committee for Medicinal Products for Human Use (CHMP)
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Hoofddorp, 2 October 2019

Subject: Withdrawal of Ekesivy 50 mg tablets
Procedure number: EMEA/H/C/005141//0000

Dear CHMP Chairman, Rapporteurs and Scientific Administrator

I would like to inform you that, at this point of time, Sun Pharmaceutical Industries Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of

Ekesivy 50 mg tablets EMEA/H/C/005141//0000

which was intended to be used for the treatment of periodic paralysis.

This withdrawal is based on the following reason:
Sun Pharmaceutical Industries Europe B.V. has decided to discontinue this application since the major objections raised cannot be answered within the available time frame.

At the present time, there are no ongoing clinical trials with **Ekesivy 50 mg tablets**.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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

Yours sincerely