



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/829978/2015
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: voriconazole

Procedure No. EMEA/H/C/PSUSA/00003127/201502

Period covered by the PSUR: 1 March 2014 to 28 February 2015



The MAH conducted a cumulative search for ephelides, lentigo and actinic keratosis and provided a tabulated overview of the retrieved cases including the requested variables of gender, age, and the outcome of the event. These data and the knowledge on the association of phototoxicity with the use of voriconazole from spontaneous cases, case reports and the action of mechanism show a possible relationship of 'ephelides', 'lentigo' and 'actinic keratosis' with voriconazole. To increase awareness and facilitate the timely recognition of photosensitivity related reactions by the healthcare professionals, it is considered that these reactions should be provided as examples of photosensitivity-related skin reactions in the product information and listed with the frequency 'not known' for ephelides and lentigo and 'rare' for actinic keratosis.

Therefore, in view of available data regarding phototoxicity reactions, the PRAC considered that changes to the product information of medicinal products containing voriconazole were warranted.