



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public statement

Exalief (eslicarbazepine acetate)

Expiry of the marketing authorisation in the European Union

On 21 April 2009, the European Commission issued a marketing authorisation valid throughout the European Union (EU) for the medicinal product Exalief (eslicarbazepine acetate), indicated for adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation.

The Marketing Authorisation Holder (MAH) responsible for Exalief was BIAL - Portela & Ca, S.A.. Exalief has not been marketed anywhere in the EU for three consecutive years from the granting of the marketing authorisation. The Agency notified by letter dated 24 July 2012 the European Commission that in accordance with Article 14(4) of Regulation (EC) N° 726/2004 ("Sunset Clause"), the marketing authorisation of Exalief has ceased to be valid.

Exalief was a duplicate application to Zebinix, which is marketed in several EU countries. The MAH will maintain the Marketing Authorisations for Zebinix.

The European Public Assessment Report for Exalief will be updated to reflect that the marketing authorisation is no longer valid.

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