



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public statement

Sabervel

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Sabervel (irbesartan) expired on 17 April 2017 following the decision of the marketing authorisation holder, Pharmathen S.A., not to apply for a renewal of the marketing authorisation.

Pharmathen S.A. confirmed that it did not apply for renewal of the authorisation due to commercial reasons.

Sabervel was granted marketing authorisation in the European Union (EU) on 17 April 2012 for the treatment of essential hypertension and the treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen.

The marketing authorisation was valid for a 5-year period.

Sabervel is a generic medicine of Aprovel. There are other generic medicinal products of Aprovel authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Sabervel will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

