EMADOC-1829012207-47705
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): pitolisant

Procedure No. EMA/PASS/0000281790

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

The MAH has fulfilled the commitment to present the final results of a non-interventional post-authorisation safety study:

A 5-year multi-center, observational post-authorisation safety study to document the utilisation of Wakix in the treatment of narcolepsy with and without cataplexy and to collect information on its long-term safety when used in routine medical practice.

The study has provided data on the long-term use and safety of pitolisant in real-world setting. The final data do not indicate any new and unexpected safety findings with pitolisant.

Therefore, in view of available data regarding the PASS final study report, the PRAC Rapporteur considered that changes to the conditions of the marketing authorisation were warranted.