



Post Authorisation Assessments

Hypersol 500 mg/g Powder for Use in Drinking Water Vm 41623/3001

22 July 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
15 May 2025	Change in the storage conditions of the finished product.
26 February 2025	One-off alignment of the product information with version 9.0.
10 February 2025	Change in qualitative or quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
12 June 2024	Change in the pharmacovigilance system master file (PSMF) location. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
04 May 2024	Submission of a new Ph. Eur. certificate of suitability for a manufacturer of the active substance.
04 May 2024	Deletion of a manufacturer of the active substance. Submission of an updated Ph. Eur. CEP for an already approved manufacturer of the active substance.
13 April 2024	Change in test procedure for the finished product.
26 March 2020	Change in shape or dimensions of the container or closure (immediate packaging). Reduction of the shelf life of the finished product as packaged for sale from 24 months to 18 months.
20 February 2020	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in shape or dimensions of the container or closure (immediate packaging). Minor changes to an approved test procedure of the finished product. Increase in batch size of the finished product.
04 April 2019	Change in the name and address of a manufacturer.
04 April 2019	Change of MAH name and address to: HUVEPHARMA SA 34 RUE JEAN MONNET ZI D'ETRICHE SEGRE 49500 SEGRE-EN-ANJOU BLEU FRANCE
19 April 2018	Renewal – UK as CMS

14 August 2017	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
02 December 2015	Change in product name in France only.