



Post Authorisation Assessments

Hypersol 500 mg/g Powder for Use in Drinking Water

Vm 41623/5001

•	28 April 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	13 April 2024	Change in test procedure for the finished product.
•	19 March 2024	Submission of a new Ph. Eur. certificate of suitability for a manufacturer of the active substance.
•	05 September 2023	Deletion of a manufacturer of the active substance. Submission of an updated Ph. Eur. CEP for an already approved manufacturer of the active substance.
•	25 August 2023	Change in qualitative or quantitative composition of the immediate packaging for a solid pharmaceutical form for a 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.

