

## **Post Authorisation Assessments**

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

	04 May 2024	Submission of a new Ph. Eur. certificate of suitability for
•	04 May 2024	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.