



## Post Authorisation Assessments

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### Otodex Skin Cream Vm 13240/4000

•	01 November 2018	Replacement of a manufacturer responsible for batch release of the finished product. Replacement of a primary packaging site of the finished product. Replacement of a secondary packaging site of the finished product. Replacement of a manufacturing site of the finished product. Addition of a manufacturer of the active substance.
•	09 May 2018	Change in the manufacturer of the active. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	21 August 2008	Change of address of the MAH
•	21 May 2008	Changes to the SPC and product literature to bring in line with new legislation.
•	21 May 2008	Change in legal category from GSL to AVM-GSL
•	28 April 2006	Renewal
•	07 September 2005	Change in the manufacturer of the active substance.
•	07 September 2005	Administrative change to the licence documentation.
•	18 December 2001	Renewal