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Post Authorisation Assessments

Moxodex 1 mg/ml Oral Solution for Sheep Vm 08749/4089

•	27 October 2022	Unlimited renewal
•	02 March 2022	Increase in the shelf-life of the finished product as packaged for sale, from 15 months to 18 months. Increase in the shelf-life of the finished product after first opening, from 3 months to 6 months.
•	25 August 2021	Qualitative and / or quantitative changes to the excipients.
•	17 June 2021	Submission of a new Ph. Eur. certificate of suitability from a new manufacturer. Submission of a new Ph. Eur. certificate of suitability from a new manufacturer.
•	26 April 2021	Change in the invented name of the veterinary medicinal product from Moxodex 1 mg/ml oral solution for sheep to Moxidectin Chanelle 1 mg/ml oral solution for sheep in Germany and Netherlands. Changes to the labelling and package leaflet.
•	04 November 2020	Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.
•	03 June 2020	Repeat Use Application to add 3 new member states.