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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

CircoMax Myco Emulsion for Injection for Pigs

Vm 42058/5013

•	27 April 2023	Removal of the warning relating to the absence of safety data during pregnancy and lactation in the SPC section 4.7 and package leaflet section 12 and replacement with 'Not applicable'. Alignment of the SPC/QRD text with the newest EU version 9.0 QRD template and GB National SPC/QRD template.
•	26 April 2023	Change in the specification limits of an active substance.
•	23 January 2023	Addition of a secondary packaging site of a finished product. Addition of a secondary packaging site of a finished product.
•	20 May 2021	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer.