



Post Authorisation Assessments

Furosivet 20 mg Tablets for Dogs and Cats Vm 04409/4007

•	30 August 2023	Change in composition of the immediate packaging for a finished product. (GB)
•	14 July 2023	<p>Change in qualitative or quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.</p> <p>Change in the specification parameters or limits of the finished product: – tightening of specification limits.</p> <p>Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product.</p> <p>Change to in-process tests or limits applied during the manufacture of the finished product: – addition of a new in-process test and limits.</p> <p>Change to in-process tests or limits applied during the manufacture of the finished product: – tightening of in-process limits.</p> <p>Changes to the quality part of the dossier: Deletion of - a manufacturing site for finished product where batch control takes place.</p> <p>Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter.</p> <p>Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g., deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product.</p> <p>Replacement or addition of a manufacturer responsible for batch release.</p> <p>Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer.</p>
•	14 July 2023	<p>Change in immediate packaging of the finished product.</p> <p>Change in pack size of the finished product.</p> <p>Change in test procedure for the finished product.</p>
•	14 July 2023	Changes to the quality part of the dossier.
•	05 December 2022	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	19 May 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.

•	03 November 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	09 April 2019	Change in RMS from UK to NL.