30 Aug 2024

Rabipur Rabies vaccine product alert for health professionals

Reports of rubber particles after reconstitution- recommendations to minimise the risk of particles

On 20 August 2024, Bavarian Nordic in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) sent a communication out to customers regarding reports of rubber particles after reconstitution of the Rabipur rabies vaccine.

Recommendations have been provided to minimise the risk of particles. Information and advice is also available on the Valneva website for health professionals - see their direct healthcare professional communication letter here.

An analysis has revealed that these particles consisted of rubber, which was transferred from the rubber stopper of the vaccine vials during the reconstitution process (so called "coring").

Reconstituted Rabipur vaccine should be carefully visually inspected and must not be administered in case of visible particles. The letter contains recommendations on how to perform the reconstitution process, with the aim of minimising the risk of particles caused by "coring".

Health professionals with product quality complaints or clinical enquiries about the Rabipur vaccine should contact the manufacturers (see letter for contact details).

Suspected adverse drug reactions can be reported to the MHRA through the Yellow Card scheme and to Valneva.

Resources

- Bavarian Nordic: Direct Healthcare Professional Communication Rabipur (Rabies vaccine inactivated)