VPA10810/003/001

Medesedan 10 mg/ml, Solution for Injection for Horses and Cattle

Variation	Summary	Date
Vet - B3 k)	VNRA - Vet - B3 k) - - Vet - B3 k) - Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	11/08/26
Vet - B3 k)	VNRA - Vet - B3 k) - - Vet - B3 k) - Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	11/08/26
Vet - B3 k)	VNRA - Vet - B3 k) - - Vet - B3 k) - Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	11/08/26
Vet - B3 k)	VNRA - Vet - B3 k) - - Vet - B3 k) - Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	11/08/26
Vet - B3 k)	VNRA - Vet - B3 k) - - Vet - B3 k) - Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	11/08/26
Vet - B3 n)	VNRA - Vet - B3 n) - - Vet - B3 n) - 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	06/07/26
Vet - B33 a)	VNRA - Vet - B33 a) - - Vet - B33 a) - Change in test procedure for the finished product to comply with Ph. Eur.: update of the test procedure to comply with the updated general monograph in the Ph. Eur.	06/07/26
Vet - B3 m)	VNRA - Vet - B3 m) - - Vet - B3 m) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of an excipient	09/06/26
Vet - G.I.2 b)	VRA-S - Vet - G.I.2 b) - b) Harmonisation of the generic/hybrid product according to article 71(1) after SPC harmonisation of the reference product - G.I.2 b) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid medicinal product following assessment of the same change for the reference product - Harmonisation of the generic/hybrid product	20/01/25

	according to article 71(1) after SPC harmonisation of the reference product	
Vet - G.I.19	VRA-R - Vet - G.I.19 - G.I.19 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet to implement the outcome of the MAH's signal management process according to Article 81(2) of Regulation (EU) 2019/6 - G.I.19 - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet to implement the outcome of the MAH's signal management process according to Article 81(2) of Regulation (EU) 2019/6	20/01/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	20/01/25
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	02/10/23
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process	23/02/23

	of the active substance; — excipient	