College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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POST AUTHORISATION INFORMATION

FOR A VETERINARY MEDICINAL PRODUCT

Planate 87.5 micrograms/ml solution for injection for pigs

Created: October 2024

PRODUCT SUMMARY

EU procedure number	NL/V/0436/001
Name, strength and pharmaceutical form	Planate 87.5 micrograms/ml solution for injection
Marketing Authorisation Holder	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer The Netherlands
Active substance(s)	Cloprostenol (as cloprostenol sodium)
ATC vetcode	QG02AD90
Target species	Pigs (sows and gilts)
Indication for use	Induction of farrowing one or two days before the estimated date of parturition

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Legal basis reviewed according to Acquis Communautaire.
Date of transfer from national authorisations to mutual recognition	22 July 2024
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	08 July 1992
Concerned Member States after transfer	BE, DE, ES, FR, IE, LU, UK(NI)
Concerned Member States for subsequent recognition procedure	-

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

GENERAL INFORMATION

Due to the date of authorisation of this product no public assessment report is available. Please be referred to the post authorisation procedures section.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which affect the referenceability and protection period of the dossier or parts of the dossier and which have been made after 27 January 2022. Please be aware that changes to the product introduced before Regulation (EU) 2019/6 started to apply as well as variations without affecting the referenceability or protection period of the dossier will not be listed below.

Sequence of significant variations

Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	Approval date

Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	Supporting information	Approval date