IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

PRID E 1.55 g vaginal delivery system for cattle

PRODUCT SUMMARY

Name, strength and pharmaceutical form	PRID E 1.55 g vaginal delivery system for cattle
Active substance	Progesterone
Marketing Authorisation Holder	LAPROVET 7, rue du Tertreau Arche d'Oé 2 37390 Notre Dame d'Oé FRANCE
Legal basis of application	Generic application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of Authorisation	24th August 2012
Target species	Cattle: cows and heifers.
Indication for use	For the control of the œstrus cycle in cows and heifers including: - Synchronisation of œstrus in cycling cattle. To be used in combination with a prostaglandin (PGF2α).
ATCvet code	QG03DA04

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA website.

I SCIENTIFIC OVERVIEW

The application is for a generic product which is identical in composition to PRID delta 1.55 g vaginal delivery system for cattle for which a marketing authorisation has been granted following European procedure FR/V/0215/001/DC (VPA 10815/013/001).
The proposed SPC for the generic product reflects that of the reference product with the exception that, at the request of the applicant, the indication (section 4.2 and section 4.9) does not include reference to use in non-cycling female cattle.

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

The quality/safety/efficacy aspects of this product are identical to PRID delta 1.55 g vaginal delivery system for cattle.

II QUALITY ASPECTS

As this is generic product which is identical to PRID delta 1.55 g vaginal delivery system for cattle for which a marketing authorisation has been granted following European procedure FR/V/0215/001/DC, the reader is referred to the publicly available assessment report for PRID delta 1.55 g vaginal delivery system for cattle in the veterinary MRIndex on the Heads of Medicines Agency website.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is generic product which is identical to PRID delta 1.55 g vaginal delivery system for cattle for which a marketing authorisation has been granted following European procedure FR/V/0215/001/DC, the reader is referred to the publicly available assessment report for PRID delta 1.55 g vaginal delivery system for cattle in the veterinary MR Index on the Heads of Medicines Agency website.

IV CLINICAL ASSESSMENT (EFFICACY)

As this is generic product which is identical to PRID delta 1.55 g vaginal delivery system for cattle for which a marketing authorisation has been granted following European procedure FR/V/0215/001/DC, the reader is referred to the publicly available assessment report for PRID delta 1.55 g vaginal delivery system for cattle in the veterinary MR Index on the Heads of Medicines Agency website.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None.