IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Galapan 75 micrograms/ml solution for injection for cattle, horses and pigs

PRODUCT SUMMARY

EU Procedure number	IE/V/0630/001/DC
Name, strength and pharmaceutical form	Galapan 75 mcg/ml solution for injection for cattle, horses and pigs
Active substance(s)	R-cloprostenol sodium
Applicant	Industrial Veterinaria S.A., Esmeralda 19, Esplugues De Llobregat, Barcelona, 08950, Spain.
Legal basis of application	Informed consent application based on Article 21 of Regulation (EU) 2019/6
Date of completion of procedure	04/06/2025
Target species	Cattle, horses and pigs
Indication for use	Cattle: - induction of luteolysis allowing resumption of oestrus and ovulation in cyclic females when used during dioestrus - synchronisation of oestrus (within 2 to 5 days) in groups of cyclic females treated simultaneously - treatment of suboestrus and uterine disorders related to a functioning or persistent corpus luteum (endometritis, pyometra) - treatment of ovarian luteal cysts - induction of abortion until day 150 of pregnancy - expulsion of mummified foetuses - induction of parturition (within the last two weeks of gestation). Horses: - induction of luteolysis in mares with a functional corpus luteum. Pigs: - induction or synchronisation of farrowing (generally within 24 to 36 hours) from day 113 of pregnancy onwards (day 1 of pregnancy is the last day of natural or artificial insemination).
ATC vet code	QG02AD90
Concerned Member States	ES

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (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 the relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the 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's website.

I. SCIENTIFIC OVERVIEW

The quality, safety, and efficacy aspects of this product are identical to those of Genestran 75 micrograms / ml solution for injection for cattle, horses and pigs (VPA10826/010/001). Cross reference is therefore made to the public assessment report for Genestran 75 micrograms / ml solution for injection for cattle, horses and pigs.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

III. SAFETY ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data referenced demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the targetspecies 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.

Changes:
None.