

IPAR



Publicly Available Assessment Report for a Veterinary Medicinal Product

Sincrovet

PRODUCT SUMMARY

EU Procedure number	IE/V/0378/001/DC
Name, strength and pharmaceutical form	Sincrovet 75 micrograms/ml solution for injection for cattle, horses and pigs
Active substance(s)	R(+)-cloprostenol (asR(+)-cloprostenol sodium)
Applicant	Industria Italiana Integratori Trei Spa Viale Corassori 62 Modena (MO) 41124 Italy
Legal basis of application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of Authorisation/ completion of procedure	28 th March 2018
Target species	Cattles, horses and pigs
Indication for use	<p>Cattle:</p> <ul style="list-style-type: none"> - 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). <p>Horses:</p> <ul style="list-style-type: none"> - induction of luteolysis in mares with a functional corpus luteum. <p>Pigs:</p> <ul style="list-style-type: none"> - 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).
ATCvet code	QG02AD90
Concerned Member States	IT

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 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 Genestran 75 µg/ml solution for injection for cattle, horses and pigs (VPA 10826/010/001). Please refer to the public assessment report for Genestran 75 µg/ml solution for injection for cattle, horses and pigs for further details.

II. QUALITY ASPECTS

See section 1.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section 1.

IV. CLINICAL ASSESSMENT

See section 1.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

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.