

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

Estrumate

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Estrumate
Active substances(s)	Cloprostenol
Applicant	Intervet Ireland Limited Magna Drive Magna Business Park, Citywest Road Dublin 24 Ireland
Legal basis of application	Full application (Article 12(3) of Directive No 2001/82/EC)
Date of <Authorisation / completion of procedure>	
Target species	Cattle, Horses
Indication for use	<p>As a synthetic prostaglandin analogue structurally related to Prostaglandin F_{2α} (PGF_{2α}), for use in cattle and horses. It causes functional and morphological regression of the corpus luteum (luteolysis) in cattle and horses followed by return to oestrus and normal ovulation.</p> <p>Cattle: <i>Therapeutic indications:</i> Suboestrus (or non detected oestrus - NDO) Induction of parturition Termination of normal pregnancy Termination of abnormal pregnancy Chronic endometritis (Pyometra) Ovarian luteal cysts <i>Controlled breeding in cattle</i></p> <p>Horses: Induction of luteolysis following early foetal death and resorption. Termination of persistent dioestrus. Termination of pseudopregnancy. Treatment of lactation anoestrus. Establishing oestrus cycles in barren/maiden mares. As an aid to stud management.</p>
ATCvet code	QG02AD90

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's website.

I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to Section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

IV. CLINICAL ASSESSMENT

See section I.

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.

Quality Changes

Summary of change (Application number)	Approval date
Change to composition of the veterinary medicinal product (CRN 7019415)	23/04/2015