IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Orbenin Dry Cow 500mg Intramammary Suspension

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Orbenin Dry Cow 500mg Intramammary Suspension
Active substance(s)	Cloxacillin
Marketing authorisation holder	Zoetis Belgium S.A 2nd Floor, Building 10 Cherrywood Business Park Loughlinstown Co. Dublin Ireland
Legal basis of application	Original authorisation based on full dossier.
Date of authorisation	01 October 1987
Target species	Cows
Indication for use	For the infusion of cows at drying off, to treat mastitis infections and to provide protection against further infections during the dry period.
ATCvet code	QJ51CF02

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 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 (EFFICACY)

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.

Safety/efficacy changes

Summary of change	Approval date
To amend the milk withdrawal period	1st October 1997

SCOPE

Type II variation to revise the withdrawal period for milk.

The HPRA reference number for this change is CRN: 7003626.

SUMMARY OF CHANGE

Prior to this variation application the recommended length of time between product administration and calving was 28 days and the withdrawal period for milk was 96 hours after calving.

Based on the findings of a new milk residue study the recommended length of time between product administration and calving was increased to 35 days. The withdrawal period for milk is unchanged at 96 hours post-calving.

The revised withdrawal period for this product is as follows:

Not intended for use within 35 days of calving. Milk for human consumption may only be taken from 96 hours after calving (that is, at the 8th milking in cows milked twice daily). If calving occurs before 35 days after last treatment, milk for human consumption may only be taken after 35 days plus 96 hours after last treatment. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered only after 28 days from the last treatment.

The SPC and product labelling have been updated accordingly.