IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Caninsulin 40 IU/ml Suspension for Injection

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Canninsulin 40 IU/ml suspension for injection
Active substance(s)	Porcine Insulin
Applicant	Intervet Ireland Ltd. Magna Drive Magna Business Park Citywest Road Dublin 24
Date of Authorisation	10/01/1997
Target species	Dogs and cats
Indication for use	The control of diabetes mellitus
ATCvet code	QA10AC03

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 Caninsulin 40 IU/ml Suspension for Injection 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.

III SAFETY ASSESSMENT

IV CLINICAL ASSESSMENT (EFFICACY)

Clinical Studies

Field Trials (information relating to Case No. 7005736)

The applicant has provided reports on a number of recent field studies in diabetic cats and dogs in addition to providing retrospective analysis of three studies submitted at the time of initial marketing authorisation application.

The retrospective analysis conducted by the applicant of Caninsulin studies performed in diabetic dogs highlights that a

significant proportion of dogs were stabilised with a dose rate of less than 1 IU/Kg bodyweight per injection. In addition, approximately one third of the dogs received insulin once daily whilst two thirds received insulin twice daily.

Two field studies were conducted over the period 1997-2001 in the U.S.A. investigating the safety and efficacy of Caninsulin therapy in 66 diabetic dogs using the initially authorised dosing regimen of 1 IU/kg bodyweight with a weight dependent supplement administered once daily. These studies reported the occurrence of hypoglycaemia in 23% of treated dogs. In addition, 66% of dogs required twice daily administration of Caninsulin by the end of the studies. Also reported was the finding that, of the 51 dogs started on Caninsulin administration once daily, 21 (41%) required the starting dose to be reduced prior to stabilisation.

In the course of the studies, an overall reduction in dose from that used to initiate therapy was required in 83% of animals. Hypoglycaemia was found more frequently in dogs administered >20 IU (medium to large breed dogs with the greater weight dependent supplement) and in these dogs a reduction in dose of 40 to 50% was required.

Based on all available data, it is concluded that a reduction in the starting dose for diabetic dogs to lie in the range 0.5 and 1.0 IU/Kg once daily is appropriate. If a twice daily dosing regimen is required, then the dose per injection should be reduced by 25% so that the total daily dose is less than doubled.

The Applicant has provided two studies in support of the variation to the dosing regimen for Caninsulin administration to cats.

One study was conducted in 2002 in the U.S.A. which included 14 diabetic cats administered an initial dose of 1 to 2 IU Caninsulin by subcutaneous injection twice daily. Following analyses of blood glucose curves, it was determined that hypoglycaemia (blood glucose < 50 mg/dL) occurred in 6 cats on a total of eight occasions during the study. Although none of the cats were reported as being symptomatic, four of the cats were given glucose supplements.

A second study investigating the safety and efficacy of Caninsulin administered to diabetic cats was conducted during the period 2005-2007 in the USA. 85 cats were administered an initial dose of 1 to 2 IU Caninsulin by subcutaneous injection twice daily. More than 16% of cats were recorded as being symptomatically hypoglycaemic.

Based upon the findings of the above studies conducted in cats, it is concluded that the currently recommended dose rates in cats should be maintained but a recommendation to restrict the maximum initial dose to 2 IU will be included in the SPC.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that Caninsulin 40 IU/ml Suspension for Injection demonstrated adequate evidence of efficacy for the approved indication 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**
Change in the starting dose for the initial treatment of diabetes mellitus in dogs and cats. **SPC Section 4.6, 4.8 and 4.9:** Revisions made to reflect the most recent information and recommendations on the use of Caninsulin in diabetic dogs and cats. HPRA case reference number 7005736	08/10/2009