IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Buprefelican Multidose 0.3 mg/ml solution for injection for dogs and cats

PRODUCT SUMMARY

EU Procedure number	IE/V/0623/001 (formerly UK/V/0562/001)
Name, strength and pharmaceutical form	Buprefelican Multidose 0.3 mg/ml solution for injection for dogs and cats
Active substances(s)	Buprenorphine
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater Netherlands
Legal basis of application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Date of Authorisation	23 September 2015 (UK) 17 November 2015 (IE)
Target species	Cats,Dogs
Indication for use	Post-operative analgesia in the dog and cat. Potentiation of the sedative effects of centrally acting agents in the dog.
ATCvet code	QN02AE01
Concerned Member States	Finland, Ireland (now RMS), Italy.

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

This was a generic application submitted under Article 13 (1) of Directive 2001/82/EC as amended, for Buprefelican vet 0.3 mg/ml solution for dogs and cats. The reference product was Vetergesic Multidose 0.3 mg/ml Solution for Dogs, Cats and Horses, marketed in the UK since February 2009.

The product is intended to treat post-operative analgesia in the dog and cat, and the potentiation of the sedative effects of centrally acting agents in the dog.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC. The product is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

II.A. Composition
The product contains buprenorphine (as hydrochloride) 0.3 mg, equivalent to 0.324 mg buprenorphine hydrochloride and the excipients chlorocresol, glucose monohydrate, hydrochloric acid, dilute, (for pH adjustment) and water for injections. The

container/closure system consists of 5, 10, 20, 50 and 100 ml vials The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are justified. The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of three simple steps in which the active substance, preservative and glucose monohydrate are dissolved in water and the pH adjusted accordingly. The solution is made up to final weight with water, filtered, and then filled into vials, prior to heat sterilisation.

II.C. Control of Starting Materials

The active substance is buprenorphine hydrochloride, an established active substance described in the European Pharmacopoeia (Ph. Eur). The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided. Certificates of Suitability were provided.

All excipients are monographed in the Ph. Eur.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.
Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product include those for appearance, colour, relative density, pH, extractable volume, identity of the preservative and the active substance and testing for impurities.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions. The re-test period for the active substance is 60 months for one supplier, and 48 months for the second. For the finished product, suitable data from three batches were provided, stored according to CVMP guidelines. In-use shelf-life stability tests were performed on two batches stored in the 5 ml and 100 ml presentations.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 10, 20, 50 and 100 ml vials: 30 months. 5 ml vials: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

This veterinary medicinal product does not require any special storage conditions.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, results of toxicological and pharmacological tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users and the environment.

III.A Safety Documentation

Environmental Safety

The product will only be provided to individual animals, therefore, the Environmental Risk Assessment Assessment stopped at Phase I. The SPC states:

- Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

IV. CLINICAL ASSESSMENT

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.I. Pre-Clinical Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, pre-clinical efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.II. Clinical Documentation

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, field studies studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the product(s) is favourable