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Publicly Available Assessment Report for a Veterinary Medicinal Product

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Torbuphanol Vet 10 mg/ml Solution for injection for horses, dogs and cats

PRODUCT SUMMARY

EU Procedure number	IE/V/0289/001/DC
Name, strength and pharmaceutical form	Torbuphanol Vet 10 mg/ml Solution for Injection for horses, dogs and cats
Active substance(s)	Butorphanol (as butorphanol tartrate)
Marketing Authorisation Holder	Zoetis Belgium S.A 2nd Floor, Building 10 Cherrywood Business Park Loughlinstown Co Dublin Ireland
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	24th October 2012
Target species	Horses, dog and cat
Indication for use	**HORSE** **As an analgesic** For relief of pain associated with colic of gastrointestinal tract origin **As a sedative** For sedation when given after the administration of certain alpha2-adrenoreceptor agonists (detomidine, romifidine). For therapeutic and diagnostic procedures such as minor standing surgery. **DOG** **As an analgesic** For relief of mild to moderate visceral pain and pain associated with post-surgical procedures. **As a sedative**

	In combination with medetomidine hydrochloride. **As a pre-anaesthetic** Pre-anaesthetic use of the product has resulted in a dose related reduction in the dose of induction anaesthetic agents, such as thiopentone sodium. As part of an anaesthetic regimen in combination with medetomidine and ketamine. **CAT** **As an analgesic** For relief of mild to moderate visceral pain. For pre-operative use to provide analgesia during surgery. For post-operative analgesia after a variety of surgical procedures. **As a sedative** In combination with medetomidine hydrochloride. As part of anaesthetic regimen in combination with medetomidine and ketamine.
ATCvet code	QN02AF01
Concerned Member States	AT, BE, BG, CZ, CY, DE, DK, EL, ES, FI, FR, HU, IT, LU, NL, PL, PT, SE, SK, NO

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 website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals 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

A.Qualitative and Quantitative Particulars

The product contains butorphanol 10 mg (as butorphanol tartrate 14.58 mg/ml) and the excipients benzethonium chloride, citric acid (monohydrate), sodium citrate, sodium chloride and water for injection.
The container/closure system consists of an amber glass type I vial of 10 or 50 ml with a chlorobutyl stopper and aluminium over seal.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B.Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C.Control of Starting Materials

The active substance is butorphanol (as butorphanol tartrate), an established active substance. 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.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

D.Control on Intermediate Products

Not applicable.

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.

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.
Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G.Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.ASafety Testing

Pharmacological Studies

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). It was confirmed that the formulation and manufacturing process for the product is identical to that of the reference product. As a result it was accepted that the product was bioequivalent to the reference product, Torbugesic 10 mg/ml Solution for Injection (VPA 10019/160/001).

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

The pharmacological aspects of this product reflect those of the reference product.

Toxicological Studies

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

User Safety

The applicant provided a user safety assessment which showed that when used in accordance with label recommendations, the product will not pose any greater risk to the user than the risks associated with use of the reference product, Torbugesic 10 mg/ml Solution for Injection.
Warnings and precautions as listed on the product literature are similar to those of the reference product and are adequate to ensure safety of the product to users.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment was required. No warnings are therefore required.
Precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.BResidues Documentation

Residue Studies

No residue depletion studies were conducted because the product that is the subject of the present application is identical in every respect (composition, manufacturing process) to the reference product. On this basis it was assumed that depletion of residues from target tissues will be identical. Consequently, exemption from the requirement to present confirmatory residue data was justified and the authorised withdrawal period for the reference product can be applied to the generic product.

MRLs

Butorphanol tartrate is included in Table 1 of the Annex of Commission Regulation (EU) No. 37/2010 (O.J. 20.1.2010, L 15/13). No MRL is required.

Withdrawal Periods

Based on the information provided above, a withdrawal period of zero days for meat in horses and zero hours for milk are justified.

IV. CLINICAL ASSESSMENT

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

IV.APre-Clinical Studies

Tolerance in the Target Species of Animals

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been claimed, efficacy studies are not provided. 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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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.