Irish Medicines Board

(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Torbuphanol Vet 10 mg/ml Solution for Injection
for Horses, Dogs and Cats
[Ireland and Poland]

Torbunal Vet 10 mg/ml Solution for Injection
for Horses, Dogs and Cats
[Denmark]

Torbugesic Vet 10 mg/ml Solution for Injection
for Horses, Dogs and Cats
[All countries except Ireland, Poland and Denmark]

MODULE 1

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 [IE, PL] Torbunal Vet 10 mg/ml Solution for injection for horses, dogs and cats [DK] Torbugesic Vet 10 mg/ml Solution for injection for horses, dogs and cats [AT, DE, FR, ES, IT, BE, LU, NL, PT, EL, CY, SK, SI, CZ, HU, SE, NO, FI, BG]
Applicant	Zoetis Ireland Limited 25/28 North Wall Quay Dublin 1 Ireland
Active substance	Butorphanol (as butorphanol tartrate)
ATCvet code	QN02AF01
Target species	Horse, 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.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the veterinary Heads of Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	24th October 2012
Concerned Member States for original procedure	AT, DE, FR, ES, IT, BE, LU, NL, PT, EL, CY, PL, SK, SI, CZ, HU, SE, NO, FI, DK, BG

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 risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

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.

D. 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.

E. Control on intermediate products

Not applicable.

F. 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.

G. 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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety 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.

Ecotoxicity

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.B Residues 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 (EFFICACY)

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.A Pre-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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

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 veterinary Heads of Agencies website (www.hma.eu).

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.

None.