Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Butomidor 10 mg/ml Injektionslösung für Pferde, Hunde und Katzen

AT/V/0005/001/DC

Last update: 20/06/2022

Modules 1-3 reflect the scientific discussion for the approval of *Butomidor 10 mg/ml Injektionslösung für Pferde, Hunde und Katzen*. The procedure was finalised on 08/10/2010. For information on changes after this date please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU procedure number	AT/V/0005/001/DC
Name, strength and pharmaceutical form	Butomidor 10 mg/ml Injektionslösung für Pferde, Hunde und Katzen
Applicant	Richter Pharma AG Feldgasse 19 A - 4600 Wels
Active substance	BUTORPHANOL TARTRATE
ATCvet code	QN02AE01
Target species	Horse, dog, cat
Indication for use	HORSE **As an analgesic** For the short term relief of pain such as colic of gastrointestinal tract origin. **As a sedative and pre-anaesthetic** In combination with α_2-adrenoceptor agonists (detomidine, romifidine, xylazine): For therapeutic and diagnostic procedures such as minor standing surgery and sedation of intractable patients. DOG/CAT **As an analgesic** For relief of moderate visceral pain e.g. pre- and post-surgical as well as post-traumatic pain. **As a sedative** In combination with α_2-adrenoceptor agonists (medetomidine). **As a pre-anaesthetic** Part of anaesthetic regime (medetomidine, ketamine).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://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.
Reference medicinal product	Butorphanol "Richter" 10 mg/ml - Injektionslösung für Pferde, Hunde und Katzen marketed by Richter Pharma AG
Date of completion of the original decentralised procedure	08/10/2010
Concerned Member States for original procedure	BE, DE, EL, ES, FI, IE, LT, NL, NO, PT, SE, SI, UK

I. SCIENTIFIC OVERVIEW

Butomidor 10 mg/ml solution for injection for horses, dogs and cats was authorized in accordance with Article 13(3) of Directive 2001/82/EC, as amended.

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. Qualitative and quantitative particulars

1 ml of the product contains:

Active substance:

Butorphanol	10 mg
(as butorphanol tartrate	14.58 mg)

Excipient:

Benzethonium chloride 0.1 mg
Sodium chloride 7.5 mg

Water for injection ad 1ml

Container/closure system: Clear glass vials with bromobutyl rubber stoppers and aluminium caps. Package sizes: 1 x 10 ml, 5 x 10 ml, 10 x 10 ml, 1 x 50 ml.

The choice of the preservative is justified.
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.

C. Control of Starting Materials

The active substance is Butorphanol, an established substance not described in the European/British Veterinary Pharmacopoeia but in the US Pharmacopoeia. 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.

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 (pharmaceuticals)

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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 for at least 60 months when stored under the approved conditions (not more than 25 °C and 60 % RH when stored in original packaging, double PE bag in Al can or in four-layer bag.

G. Other Information

Not applicable

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on pharmacodynamics and pharmacokinetics are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

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 / the environment / consumers.

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, results of toxicological tests are not required.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, results of pharmacodynamic and pharmacokinetic tests are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

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

Environmental Risk Assessment

Phase I

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The environmental risk assessment demonstrated that use of Butomidor would not result in extensive environmental exposure.

Warnings and precautions as listed on the SPC and product literature are adequate to ensure safety to the environment when the product is used as directed.

Conclusion

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT (EFFICACY)

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

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, pharmacodynamic and pharmacokinetic studies are not required.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, tolerance studies are not required.

IV.B Clinical Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on clinical efficacy are not required.

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 Heads of Veterinary Medicines 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.

Significant changes

Summary of change **(Application number)**	**Approval date**
The marketing authorization was renewed unlimited. (AT/V/0005/001/R/001)	20/08/2015
Repeat use procedure to include CMS DK, FR, IS, LV. (AT/V/0005/001/E/001)	28/06/2017
Adaptation of SmPC after AT/V/0005/001/E/001 (AT/V/0005/001/IB/009)	21/01/2022
The marketing authorization for DK, FR, IS, LV was renewed unlimited. (AT/V/0005/001/R/002)	17/05/2022
*** No significant changes since ***	