Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Alvegesic vet. 10 mg/ml solution for injection for horses, dogs and cats

AT/V/0003/001/DC

Last update: 13/11/2018

Modules 1-3 reflect the scientific discussion for the approval of Alvegesic vet. 10 mg/ml solution for injection for horses, dogs and cats. The procedure was finalised on 25/02/2009. For information on changes after this date please refer to module 4.

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 1

PRODUCT SUMMARY

EU procedure number	AT/V/0003/001/DC
Name, strength and pharmaceutical form	Alvegesic vet. 10 mg/ml solution for injection for horses, dogs and cats
Applicant	Alvetra u. Werfft GmbH Boltzmanngasse 11 A-1090 Vienna
Active substance	BUTORPHANOL TARTRATE
ATCvet code	QN02AF01
Target species	Horses, dogs and cats
Indication for use	HORSE As an analgesic: For relief of moderate to severe abdominal pain (alleviates abdominal pain associated with colic of gastrointestinal origin). As a sedative: For sedation after the administration of certain alpha2-adrenoceptor agonists (detomidine, romifidine). DOG As an analgesic: For relief of moderate visceral pain. As a sedative: For sedation in combination with certain alpha2-adrenoceptor agonists (medetomidine). As a pre-anaesthetic: For pre-anaesthesia as sole agent and in combination with acepromazine. As an anaesthetic: For anaesthesia in combination with medetomidine and ketamine. CAT As an analgesic for the relief of moderate pain: For pre-operative analgesia in combination with acepromazine/ketamine or xylazine/ketamine. For post- operative analgesia after small surgical procedures. As a sedative: For sedation in combination with certain alpha2-adrenoceptor agonists (medetomidine). As an anaesthetic: For anaesthesia in combination with medetomidine and 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	Torbugesic 1% w/v Solution for Injection
Date of completion of the original decentralised procedure	25/02/2009
Concerned Member States for original procedure	BE, CZ, DE, FI, IE, IS, IT, NL, PL, SE, SI, UK

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 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

The product contains:

10 mg Butorphanol (equivalent to 14.58 mg Butorphanol tartrate) as active substance and the excipients benzethonium chloride, citric acid monohydrate, sodium citrate, sodium chloride and water for injections.

The container/closure system is a cardboard box with 1 glass (Type II) vial of 10 ml with a bromobutyl rubber stopper and aluminium cap.

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.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is Butorphanol. 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)

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 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

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years

In-use shelf life

Shelf life after opening the immediate packaging: 28 days

Special precautions for storage

Keep vial in the outer carton in order to protect from light. Do not refrigerate or freeze.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

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.

Toxicological Studies

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required.

User Safety

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, a detailed user safety is not required.

Nevertheless the applicant provided a satisfactory user risk assessment, identifying the risk to the users of the product and the potential routes of exposure. This showed that the most likely routes of exposure to the product would be via accidental injection / self-injection. The most frequent adverse effects of butorphanol in humans are drowsiness, sweating, nausea, dizziness and vertigo and may occur following unintended self-injection. The risks have been identified and appropriate warnings are included in the SPC and product literature.

Environmental Risk Assessment

In the safety expert statement the applicant has concluded that environmental safety is unchanged and no reports regarding environmental impact have become available. As a result environmental safety has no adverse impact on the benefit/risk assessment for the product. The disposal advice given in the SPC is considered to be sufficient.

Withdrawal Periods

Horse:	"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."	Meat

and offal: Zero days
Milk: Zero hours

IV. CLINICAL ASSESSMENT (EFFICACY)

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required, as it has already been presented for 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 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**
This marketing authorization was extended to other MS (BG, EE, ES, FR, HU, LT, LV, NO, PT, RO, SK) and therefore reassessed. (AT/V/0003/001/E/001)	23/03/2011
This marketing authorization was renewed unlimited. (AT/V/0003/001/R/001)	20/02/2014