Ravimiamet
State Agency of Medicines

Hinnangu kokkuvõte

19.06.2014 anti müügiluba Maxx Pharma OÜ veterinaarravimile Sedastop Vet, 5 mg/ml süstelahus.

Müügiluba taotleti riikliku protseduuri kaudu.

Tegemist on retseptiravimiga, mida kasutatakse medetomidiini või deksmedetomidiini rahustava ja muude toimete lõpetamiseks.

Ravimit Sedastop Vet kasutatakse koertel ja kassidel.

Ravimi Sedastop Vet toimeaine on atipamesool, mis kuulub selektiivsete α2-antagonistide rühma.

Ravimile anti müügiluba, kuna Sedastop Vet kasutamisest oodatav kasu ületab võimalikud riskid.

Avalik hinnanguaruanne on leitav järgnevatelt lehekülgedelt.

Public Assessment Report

Scientific discussion

SEDASTOP VET
atipamezole

Date: 25.06.2014

This module reflects the scientific discussion for the approval of Sedastop Vet. The procedure was finalised at 19.06.2014. For information on changes after this date please refer to the module 'Update'.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, Estonia has granted a marketing authorisation for Sedastop Vet, 5 mg/ml, solution for injection, from Maxx Pharma OÜ.
Sedastop Vet contains the active substance atipamezole hydrochloride 5 mg/ml. This is a sedative, which acts as a α2- antagonist. The product is intended for intravenous, intramuscular and subcutaneous administration. Doses depend on the level of sedation required and on specific combinations with other products. The product is indicated for restraint, sedation and analgesia in dogs and cats.
A comprehensive description of the indications and posology is given in the SPC.
The marketing authorisation has been granted pursuant to Article 13(1), generic application, of Directive 2001/82/EC, as amended.

II. QUALITY ASPECTS

II.1 Introduction

Sedastop Vet contains 5 mg/ml of atipamezole hydrochloride and is presented in form of solution for injection.
The excipients are methyl parahydroxybenzoate, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.
Sedastop Vet is presented as a clear, colourless, sterile, aqueous solution.

The solution for injection is packed in 10 ml clear glass vials (type I) which are closed with bromobutyl rubber closures secured with aluminium flip-off caps.

II.2 Drug Substance

Atipamezole hydrochloride
Atipamezole is a potent α_2 adrenergic receptor antagonist which is used as veterinary drug substance to reverse the sedative effect produced by the α_2 agonist medetomide.
The hydrochloride salt of atipamezole is a white or almost white crystalline powder, sparingly soluble in water.
The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.
The active substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.
Stability studies under ICH conditions have been conducted and the data provided are sufficient to confirm the re-test period.

II.3 Medicinal Product

Sedastop Vet is solution for injection containing 5 mg/ml of atipamezole hydrochloride. Sedastop Vet is presented as a clear, colourless, sterile, aqueous solution.
The development of the product has been described, the choice of excipients is justified and their functions explained. The excipients used are of pharmacopoeial quality and comply with the current edition of Ph. Eur.
The information provided with regard to manufacturing process of the veterinary medicinal product is considered adequate. In-process controls with acceptance criteria are presented. Process validation has been carried out and the results are satisfactory.

The drug product specifications are considered acceptable. The analytical methods are described and validated. Batch analysis results have been provided for 3 batches.
The solution for injection is packed in 10 ml clear glass vials (Type I glass) which are closed with bromobutyl rubber closures secured with aluminium flip-off caps.
The conditions used in the stability studies are according to the ICH guideline. The proposed shelf-life of 36 months can be accepted. This medicinal product should be stored in original package to protect from light. Once the container is first opened a shelf-life of 28 days applies.

III. SAFETY AND RESIDUES ASSESSMENT

The application is made in accordance with Article 13(1) of Directive 2001/82/EC as amended. The essential similarity between Sedastop Vet and the reference product is based on identical formulations of both products.

III.A SAFETY

Pharmacological studies
As this is a generic application according to Article 13 of Directive 2001/82/EC as amended by 2004/28/EC, pharmacological studies are not required.

Toxicological Studies
As this is a generic application according to Article 13 of Directive 2001/82/EC as amended by 2004/28/EC, toxicological studies are not required.

User safety
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. These are the same as for the reference product:
Avoid skin or mucosal contact with the product. In the case of accidental contact of the product rinse the skin or mucosa with plenty of water immediately.

Ecotoxicity/environmental risk assessment (ERA)
The applicant provided the environmental impact assessment (Phase I) in compliance with the Guideline on Environmental Impact Assessment (EIAS) for Veterinary Medicinal Products – Phase I (Ref: CVMP/VICH/592/98-FINAL) and Revised Guideline on Environmental Impact Assessment for Veterinary Medicinal Products – In support of the VICH Guidelines GL6 and GL38 (Ref: EMEA/CVMP/ERA/418282/2005-Rev.1) which showed that no further assessment is required. In short it is correctly concluded that the assessment can stop at phase I since the product is intended for use in the target species cats and dogs, i.e. non-food animals only.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

Conclusion
As this is a generic application and bioequivalence with a reference product has been demonstrated, pharmacokinetic and toxicological studies are not required.
The toxicological aspects of this product are identical to the reference product.
Warnings and precautions as listed on the product literature are the same as those of the reference product.

It can be concluded that Sedastop Vet is safe for the target species, human and environment providing that the product is used in accordance with the instructions given in the product literature.

III.B RESIDUES
Sedastop Vet is intended for use in dogs and cats. Thus, residue studies are not applicable.

IV. EFFICACY ASSESSMENT

The application is made in accordance with Article 13(1) of Directive 2001/82/EC as amended. The essential similarity between Sedastop Vet and the reference product is based on identical formulations of both products. The product is indicated for the reversal of the sedative and other effects of medetomidine or dexmedetomidine in dogs and cats.

IV.A Pre-Clinical Studies

Pharmacology
As this is a generic application according to Article 13 of Directive 2001/82/EC as amended by 2004/28/EC, pharmacological studies are not required.

Tolerance in the Target Species of Animals
As this is a generic application according to Article 13 of Directive 2001/82/EC as amended by 2004/28/EC, tolerance studies are not required.

IV.B Clinical Studies
As this is a generic application according to Article 13 of Directive 2001/82/EC as amended by 2004/28/EC, clinical studies are not required. The essential similarity between Sedastop Vet and the reference product is based on identical formulations of both products.

Conclusion
As this is a generic application and bioequivalence with a reference product has been demonstrated, pharmacological, toxicological and clinical studies are not required.
The clinical aspects of this product are identical to the reference product.
Warnings and precautions as listed on the product literature are the same as those of the reference product.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Based on the submitted data presented by the applicant it can be concluded that the benefit/risk evaluation of the product is favourable. Sedastop Vet is safe and effective for indicated claims in the target species and the safety of the product for humans and the environment is acceptable, providing that the product is used in accordance with the instructions given in the product literature.