Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Sedanol 40 mg/ml solution for injection for pigs

Date: 11.01.2023

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0300/001/DC
Name, strength and pharmaceutical form	Sedanol 40 mg/ml solution for injection for pigs
Applicant	VetViva Richter GmbH Durisolstraße 14 A-4600 WELS Austria
Active substance	Azaperone
ATC Vetcode	QN05AD90
Target species	Pig
Indication for use	A neuroleptic sedative for pigs: For the use in animals with aggressive behaviour -following re-grouping -in sows (devouring of piglets by the sow) For the use in animals with stress and prevention of stress -cardiovascular stress -transport-related stress Obstetrics As pre-medication in local or general anaesthesia For relief of symptoms in animals with nutritional muscular dystrophy

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23 October 2019
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	AT, BG, CZ, DK, EE, EL, FI, HR, HU, IE, IS, IT, LT, LV, NO, PL, PT, RO, SE, SI, SK, and 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.

The safety and efficacy aspects of this product are identical to the reference product Stresnil (Elanco GmbH). The initial application for Stresnil (authorisation number: 6762247.00.00) was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 40 mg /ml azaperone for veterinary use as active substance and the excipients methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium metabisulfite, tartaric acid, sodium hydroxide and water for injections.

The product is packaged in 50 ml and 100 ml clear glass vials (Ph.Eur. type I) closed with chlorobutyl rubber stopper (Ph. Eur. type I) and sealed with aluminium cap.

The choice of the formulation and the presence of preservative are 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.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is azaperone for veterinary use, an established active substance described in the European 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

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.

The claim of a 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at 25 °C.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and bioequivalence with the reference product can be assumed, results of safety tests other than those supporting the user risk assessment are not required.

The applicant has provided a user risk assessment in compliance with the relevant guideline, which identifies the relevant users of the product and routes of user exposure. Due to the pharmacological and toxicological properties of the active substance and excipients, sedative effects, hypersensitivity reactions, dermal and eye irritation as well as possible harm to the foetus of pregnant users are identified as relevant user risks. Moreover, as no data are available regarding a possible transfer of azaperone to breast milk, a risk for breastfed children cannot be excluded. The warnings and precautions as listed in the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the initial predicted environmental concentration in soil (PECsoil, initial = 17.4 µg/kg) is less than 100 µg/kg.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted as this is a generic application submitted according to Article 13 (1) of Directive 2001/82/EC as amended and bioequivalence with the reference product can be assumed.

MRLs

Azaperon is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification
Azaperone	Sum of azaperone and azaperol	Porcine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Skin and fat Liver Kidney	NO ENTRY	Agents acting on the nervous system/Agents acting on the central nervous system

All excipients are included either in Table 1 of the Annex of Commission Regulation (EU) No 37/2010 with a “No MRL required” status for all food producing species or in the “Out of scope list”.

Withdrawal Periods

Based on the outcome of referral procedure EMEA/V/A/138, a withdrawal period of 18 days for meat and offal in pigs is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product Stresnil has been established, efficacy studies are not required. The product literature has been updated as requested by the RMS and CMSs.

IV.A Pre-Clinical Studies

This is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended. The reference and the generic product are aqueous solutions for intramuscular injection. They are comparable in terms of the qualitative and quantitative composition of the active substance and excipients and the pharmaceutical form. Therefore, exemption from need to demonstrate bioequivalence *in vivo* according to section 7.1 b of the Guideline for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMEA/CVMP/016/00-Rev. 2) is justified and data on pharmacodynamics, pharmacokinetics or target animal tolerance are not required. The pharmacodynamics and pharmacokinetic properties of the product are properly reflected in the SPC in line with the reference product.

Tolerance in the Target Species of Animals

The product literature accurately reflects the adverse effects which might be expected.

IV.B Clinical Studies

Since this is a generic application according to Article 13(1) of Directive 2001/28/EC as amended, and bioequivalence is established, no data on clinical efficacy are 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 benefit risk profile for the target species is favourable and the quality and safety of the product for humans and for 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 Medicinal 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.

Safety/efficacy changes

Summary of change **(Type; application number)**	**Section updated in Module 3**	**Approval date**
DE/V/0300/001/IA/001 – Variation to implement the outcome of the referral procedure EMEA/V/A/138	IIIB	10.12.2020
E.z - ADMINISTRATIVE CHANGES (Transfer the marketing authorisation in DE from Richter Pharma AG to VetViva Richter GmbH)	N/A	11.01.2023