College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Stresoron 40 mg/ml solution for injection for pigs

PRODUCT SUMMARY

EU procedure number	NL/V/0427/001/DC
Name, strength and pharmaceutical form	Stresoron 40 mg/ml solution for injection for pigs
Applicant	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany
Active substance(s)	Azaperone
ATC vetcode	QN05AD90
Target species	Pigs
Indication for use	1. For the use in animals with aggressive behaviour - following re-grouping - in sows (devouring of piglets) 2. For the use in animals with stress and prevention of stress - cardiovascular stress - transport-related stress 3. Obstetrics 4. Premedication for local or general anaesthesia 5. For relief of symptoms in animals with nutritional muscular dystrophy

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	- Stresnil 40 mg/ml oplossing voor injectie voor varkens - Stresnil 40 mg/ml Injektionslösung für Schweine
Marketing authorisation holder	Elanco Animal Health GmbH
MS where the RP is or has been authorised	NL / DE
Marketing authorisation number EU procedure number	REG NL 3153/ 6762247.00.00
Date of authorisation	August 1997 / July 2005
Date of completion of the original decentralised procedure	2 July 2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE, CZ, DE, ES, FR, HU, IE, PL, SK, UK(NI)
Concerned Member States for subsequent recognition procedure	-
Withdrawn CMS during original decentralised procedure	-

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

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

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The proposed solution for injection contains 40 mg/ml azaperone and the excipients methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium metbisulfite, tartaric acid, sodium hydroxide and water for injection. The solution for injection is a clear, greenish-yellow solution.

The product is packed in 50 and 100 ml colourless type I glass bottles, fitted with chlorobutyl rubber stoppers and aluminium caps. The secondary package is a carboard box.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

The VMP is manufactured using conventional manufacturing techniques. The tests performed during manufacture are described and regarded to be acceptable. Suitable validation results on two production scaled batches have been provided.

C. Production and control of starting materials

The active substance is azaperone, an established active substance described in the European Pharmacopeia. 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 VMP.

D. Control tests carried out on isolated intermediates during the manufacturing process

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 VMP.

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 tests

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 VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of safety and residue tests are not required.

The safety and residue aspects of this VMP are identical to the reference VMPs.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users / the environment / consumers.

A. Safety tests

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that the VMP may cause hypersensitivity reactions and sedation in case of accidental self-injection. Furthermore it was concluded that the product should not be handled by pregnant women due to effects of azaperone on the fetus.

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

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 = 17.38 µg/kg) is less than 100 µg/kg.

B. Residues documentation

Residue tests

No residue depletion studies were conducted because bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

Azaperone 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 provision**
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

Withdrawal Periods

Based on the data provided above, a withdrawal period of 18 days for meat in pigs is justified.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

None.