FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

SOMNIPRON 10 mg/ml SOLUTION FOR INJECTION FOR HORSES AND CATTLE

FR/V/0228/001/DC
CMS: ES, PT, IT

Date: *10 January 2012*

"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

Name, strength and pharmaceutical form	SOMNIPRON 10 MG/ML SOLUTION FOR INJECTION FOR HORSES AND CATTLE
Applicant	VETPHARMA ANIMAL HEALTH LES CORTS, 23 08028 BARCELONA SPAIN
Active substance(s)	Detomidine hydrochloride
ATC Vetcode	QN05CM90
Target species	Horses and cattle
Indication for use	For the sedation and slight analgesia to facilitate physical examinations and treatments such as minor surgical interventions. Premedication prior to the administration of injectable or gaseous anaesthetics. Detomidine can be used in the following cases: - Medical examinations (such as endoscopy, rectal and reproductive tract examinations, radiography). - Minor surgical procedures (such as dental or tendinous treatments, excision of skin tumours, treatment of teats or various injuries). - Before surgery or administration of medication (such as gastric intubation, shoeing).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

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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
Date of completion of the original decentralized procedure	23/09/2011
Concerned Member States for original procedure	AT, DE, ES, HU, IT, PT

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, 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. Composition

The product contains 8.36 mg/ml detomidine (hydrochloride) as active substance, and the excipients methyl parahydroxybenzoate, sodium chloride and water for injections

The container/closure system is a clear glass vial fitted with a bromobutyl rubber stopper with aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

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 from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is detomidine hydrochloride 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. 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.

G. 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.

An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference product DOMOSEDAN of ORION CORPORATION.

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

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

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

The toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has not provided a user safety assessment which is acceptable because the tested product and the reference product have similar formulations.

The user safety 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 and are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

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

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted since the tested product is bioequivalent to the reference product and has a similar formulation.

MRLs

a. active substances

The active substance, detomidine, is included in table 1 of the MRL regulation 470/2009, as follows:

DETOMIDINE						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
Not applicable	Bovine, Equidae	No MRL required but a	Not applicable	For therapeutic use only	No entry	37/2010 of 22.12.2009

An ADI has been calculated for detomidine**:** 0.3 µg/kg (18 µg/person).

b. excipients

The MRL status of the excipients of the tested product are indicated in the following table:

Excipient	**MRL status**	**ADI**
Sodium chloride	Table 1, no MRL required	-
Methyl parahydroxybenzoate (E218)	Table 1, no MRL required	-

Withdrawal Periods

The tested product will be applied identical withdrawal periods than the reference product that is:
Horses and cattle:
Meat and offal: 2 days
Milk: 12 hours

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because the tested product and the reference product have similar formulations and are bioequivalent.

The tolerance aspects of this product are identical to the reference product

Based on the conclusion made for the reference product, the product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

As this is a generic application according to Article 13, 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.

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.