AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

Agence nationale du médicament vétérinaire (ANMV) – French agency for veterinary medicinal products
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bromhex-Air forte oral powder for cattle, pigs, chickens, turkeys and ducks

DATE: 02/04/2021

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0426/002/DC
Name, strength and pharmaceutical form	Bromhex-Air forte oral powder for cattle, pigs, chickens, turkeys and ducks
Applicant	Pharmanovo Veterinärarzneimittel GmbH Liebochstrasse 9 8143 Dobl Austria
Active substance(s)	Bromhexine hydrochloride
ATC Vetcode	QR05CB02
Target species	Cattle (calves), pigs, chickens, turkeys and ducks
Indication for use	Mucolytic treatment of congested respiratory tract.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	03/03/2021
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	DE, HU, IE, IT, PL and UK(NI)

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 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 22,775 mg/g bromhexine (as bromhexine hydrochloride) and excipients glucose monohydrate and citric acid.
The packaging of the finished product is as described on the SPC. 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 bromhexine 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

A re-test period for the active substance is set in the certificate of suitability issued by EDQM.
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 after first opening and an in-use shelf-life after dilution as detailed on the SPC have been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL) (*for pharmaceuticals only)*

III.A Safety Testing

Toxicological Studies

As this is a hybrid 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 provided a user safety assessment in compliance with the relevant guideline.

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

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required as all calculated PECsoil are below the trigger threshold of 100 µg/kg.

III.B Residues documentation

Residue Studies

As this is a hybrid application according to Article 13 of Directive 2001/82/EC as amended, and bioequivalence with the reference product has been demonstrated, it is not necessary to perform specific depletion study.

MRLs

The active substance bromhexine is included in table 1 of the MRL regulation 37/2010, as follows:

Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification	Regulation
Not applicable	Bovine, porcine, poultry	No MRL required	Not applicable	Nor for use in animals from which milk or eggs are produced for human consumption	No entry	37/2010 of 22.12.2009

A toxicological acceptable daily intake (ADI) of 0.3 mg per person was established for bromhexine.

The composition of the candidate product BROMHEX-AIR BASIC 10 MG/G ORAL POWDER FOR CATTLE, PIGS, POULTRY, DOGS AND CATS is acceptable according to the European Regulation 470/2009.

Withdrawal Periods

As this is a generic (hybrid) application according to Article 13, and bioequivalence with a reference product has been demonstrated, the same withdrawal period are justified:

Cattle
Meat and offal: 2 days
Not authorised for use in animals producing milk for human consumption.
Pigs
Meat and offal: Zero days.

Chickens, turkeys and ducks
Meat and offal: zero days
Not for use in birds producing eggs for human consumption during and 4 weeks before the laying period.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a hybrid application according to Article 13 of Directive 2001/82/EC as amended, and bioequivalence with the reference product has been demonstrated, efficacy studies are not required.

The product is indicated for the same claims and at the same the posology as 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.