IPAR

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vetmulin 20g/kg Premix for medicated feeding stuff for pigs.
IE/V/0214/001/DC

PRODUCT SUMMARY

EU Procedure number	IE/V/0214/001/DC
Name, strength and pharmaceutical form	Vetmulin 20g/kg Premix for medicated feeding stuff for pigs. IE/V/0214/001/DC
Applicant	Huvepharma NV Uitbreidingsstraat 80 2600 Antwerpen Belgium
Active substance(s)	Tiamulin as tiamulin hydrogen fumarate
ATC Vetcode	ATC Vet Code: QJ01XQ01 Pharmacotherapeutic group: antibacterials for systemic use, pleuromutilins
Target species	Pigs
Indication for use	For treatment and prevention, when the disease is present at herd level, of swine dysentery caused by *Brachyspira hyodysenteriae* sensitive to tiamulin. The presence of disease in the herd should be established before use.

PUBLIC ASSESSMENT REPORT

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Legal basis of original application	Generic, Article 13(1) Reference product: Tiamutin Premix 2% (Novartis)
Date of completion of the original mutual recognition procedure	Not applicable.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	AT, BE, CZ, DE, DK, EL, ES, FR, HU, IT, NL, PL, PT, UK, BG, RO

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

II QUALITY ASPECTS

A. Composition

Tiamulin hydrogen fumarate 20 g per kg in a formulation containing pregelatinised starch and wheat starch.

5 kg or 20 kg polyethylene bags placed inside three-ply paper bags.

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.

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

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is Tiamulin hydrogen fumarate 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

No materials of animal origin are used in its production in compliance with EMEA/410/01 rev 02.

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.

The in-feed shelf life for meal and pellets as detailed in the SPC are supported by appropriate in-feed stability 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
The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). Vetmulin 20g/kg Premix for medicated feeding stuff for pigs contains the same qualitative and quantitative composition in terms of active ingredient as the reference products Tiamutin Premix 2% (Novartis). *In vitro* dissolution data provided in support of the application show that the test product (Vetmulin 2% Premix) is bioequivalent to the reference product (Tiamutin 2% Premix); therefore, Vetmulin Premix can be expected to have similar pharmacokinetic properties and, consequently, the same efficacy and safety profile as Tiamutin Premix.

Toxicological Studies
As this application is made in accordance with Article 13(1) of Directive 2001/82/EC as amended, and the product is bioequivalent to the reference product, no toxicological studies have been presented.

User Safety
The provisions of the Guideline on user safety for veterinary medicinal products (EMEA/CVMP/543/03-FINAL) do not apply to applications made in accordance with Article 13(1) of the Directive. It can be assumed that user safety aspects will be similar to those of the reference product. The proposed warnings are appropriate given the irritant nature of the active substance and can be accepted.

Ecotoxicity
An environmental risk assessment in compliance with the relevant guidelines was presented. The assessment concluded that, when used in accordance with label instructions, the risk to the environment is acceptable. No special warnings are therefore required.

III.B Residues documentation
As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety and residue tests are not required. It can be assumed that residue depletion profile will be similar for both products.

The proposed withdrawal period for Vetmulin has been agreed taking into account the differences in withdrawal period for the reference product in different Member States.

IV CLINICAL ASSESSMENT (EFFICACY)

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).

In vitro dissolution data provided in support of the application show that the test product (Vetmulin 2% Premix) is

bioequivalent to the reference product (Tiamutin 2% Premix); consequently, it can be concluded that the systemic effects of the two products in respect of efficacy and target animal tolerance will be the same.

The proposed SPC text is in line with the authorised SPC of the reference product in the RMS. However, in order to achieve harmonisation between the Member States concerned, certain amendments to the indications and posology were agreed.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The overall benefit/risk assessment is positive.

VI POST-AUTHORISATION ASSESSMENTS

Not applicable.