Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Taneven 300 mg/ml
suspension for injection

Date: 29 July 2020

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0337/001/DC
Name, strength and pharmaceutical form	Taneven 300 mg/ml suspension for injection
Applicant	WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG Siemensstr. 14 D-30827 Garbsen Germany
Active substance(s)	Benzylpenicillin procaine monohydrate
ATC Vetcode	QJ01CE09
Target species	Horses, cattle, sheep, goats, dogs and cats
Indication for use	For the treatment of the following infections caused by bacteria susceptible to benzylpenicillin: - infections of the respiratory system - infections of the urinary and reproductive system - infections of the skin and claws - infections of the joints - septicaemia

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 Decentralised procedure	29 July 2020
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for DCP	AT, BG, HU, IT, LU, PL, 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; any 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. Qualitative and quantitative particulars

The product contains 300.00 mg/ml Benzylpenicillin, procaine $1H_2O$ as active substance and 2.84 mg/ml Methyl-4-hydroxybenzoate and 0.32 mg/ml Propyl-4-hydroxybenzoate as preservatives. Further excipients are (3-sn- Phosphatidyl)cholin (Lecithin), Povidone K 25, Sodium citrate 2 H_2O, Sodium thiosulphate 5 H_2O, Propylene glycol, Disodium edetate 2 H_2O, Potassium dihydrogen phosphate and Water for injections.

The product is packed in 100 ml siliconised glass bottles (glass type II) with a bromobutyl rubber stopper and an aluminium flip-off seal in a cardboard box.

The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of the preservatives 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 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 Benzylpenicillin, procaine $1H_2O$ is 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.

A copy of the valid CEP “Benzylpenicillin, procaine, lecithin coated (1%), sterile” has been provided by the manufacturer.

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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological tests are not required.

The safety 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. Although both products are identical, additional user safety phrases were included in accordance with current European standards. Warnings and precautions as listed on 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 concentrations in soil, based on a treatment duration of 3 days, are less than 100 µg/kg.

It can be expected that Taneven will not pose a risk to the environment when used in accordance with the SPC.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because 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

Benzylpenicillin and Procaine are 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
Benzylpenicillin	Benzylpenicillin	All food producing species	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to 'muscle and skin in natural pro-portions'. MRLs for fat, liver and kidney do not apply to fin fish. For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which eggs are produced for human consumption.	Anti-infectious agents/Antibiotics

Procaine	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY

All excipients are included either in Table 1 of the Annex to 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 data provided above, the following withdrawal periods are justified:

Horse:
Meat and offal: 10 days
Not authorised for use mares producing milk for human consumption.

Cattle, sheep and goat:
Meat and offal: 10 days
Milk: 120 hours (5 days)

IV. CLINICAL ASSESSMENT (EFFICACY)

This is a generic application according to Article 13(1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, in accordance with section 7.1.d of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMEA/CVMP/016/00-Rev.3).
Therefore, efficacy and target animal safety studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13(1), no target animal tolerance studies were conducted.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

The bibliography information provided suggests that there are no concerns on resistances for benzylpenicillin.
Adequate warnings and precautions appear on the product literature.

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.

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).