ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

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1. NAME OF VETERINARY MEDICINAL PRODUCT

TYLOSINA 200 BMP - premix for medicated feed granular powder for oral use for swine and broilers.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION/Kg

1Kg product contains:

Active ingredient:

Tylosine (from tylosine tartrate) 200g

For full list of excipients see paragraph 6.1

3. PHARMACEUTICAL FORM

Premix for medicated feed, granular powder for oral use to be administered mixed in feed.

4. CLINICAL PARTICULARS

4.1 Target species

Swine, broilers.

4.2 Indications for use, specifying the target species

Therapy and prophylaxis of infections caused by tylosine sensitive organisms in particular: necrotic enteritis and enzootic pneumonia in swine; respiratory chronic disease in broilers.

For information regarding swine dysentery see section 4.5.

4.3 Contraindications

Unknown.

4.4 Special warnings for each target species

Use only after verifying ascertained sensitivity of the germs to the active substance. An antibiogram is recommended before starting the treatment.

4.5 Special precaution for use

Special precautions for use in animals

Do not use in laying hens producing eggs for human consumption.

A high rate of *in vitro* resistance has been demonstrated in European strains of *brachyspira hyodysenteriae* implying that the product will not be sufficiently efficacious against swine dysentery.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Using common rules for preparation and administration of the product particular precautions for the operator are not necessary, anyhow it’s suggested to avoid inhalation or direct contact; it’s suggested to use protective clothes and gloves while handling the product; do not eat, drink or smoke during handling; wash hands after use.

4.6 Adverse reactions (frequency and seriousness)
None reported.

4.7 Use during pregnancy, lactation or lay
Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction
Cross resistance has been observed of tylosine with desmicosine.

4.9 Amount to be administrated and administration route
The drug has to be accurately administered in feed at the daily dosage here below listed. The concentration in feed has to be adjusted according to the real body weight of the animals and effective consumption of feed.
SWINE: 10-12mg tylosine (equivalent to 50-60mg Tylosina 200 BMP)/kg b.w. for 8 days as per veterinary prescription.
BROILERS: 25mg tylosine (equivalent to 125mg Tylosina 200 BMP)/kg b.w. for 3-5 days as per veterinary prescription.

4.10 Overdose (symptoms, emergency measures, antidotes), if necessary
Toxic effects associated with over dosage are not known, so it is suggested not to exceed the recommended dosages.

4.11 Withdrawal period(s)
Meat and offal: swine 8 days; broilers 12 days.

Not authorised for use in birds producing eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic Group: systemic antibiotics
ATCvet Code: QJ01FA90

5.1 Pharmacodynamic properties
Tylosine is a macrolide antibiotic with a broad action spectrum with a prevalent bacteriostatic activity, that it's shown by inhibition of the protein synthesis of bacteria by a link with the ribosome subunits 50S. Its main activity is against *mycoplasma* and some Gram negative bacteria.

5.2 Pharmacokinetic particulars
When administered orally, tylosine is quickly absorbed at intestinal level, with a serum peak after two hours. The elimination is through bile, urines and faeces.

6. PHARMACEUTICAL PARTICULAR

6.1 List of excipients
Polysorbate
Polyethylenglycol 300
Granular Calcium carbonate

6.2 Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary product as packaged for sale: 24 months. The expiration date refers to the product correctly stored in the immediate packaging.

Shelf life after first opening of immediate packaging: 2 months, if it's correctly stored.

Shelf life after incorporation into meal or pelleted feed: 6 months

6.4 Special precautions for storage

Store in dry and cool place far from heating source.
After use keep the container tighly closed.
Keep out of the reach of children.

6.5 Nature and composition of immediate packaging

Multilayer bag: three sheets paper-sandwich printed white paper and avana kraft, polyethylene (PE), kraft avana – 25Kg.

6.6 Special precautions for the disposal of the unused veterinary medicinal product or waste materials from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder

DOX-AL ITALIA SPA
Legal seat: Piazzale Cadorna 10-20123 Milano, Italy.
Manufacturing site: Via Mascagni 6 – 20884 Sulbiate (MB).
Tel: + 39 03962051
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8. Number of marketing authorization

17394

9. Date of first Authorization/ Renewal Marketing Authorization

Date of first authorization: 05/11/1997
Date of last renewal: 09/12/2014

10. Date of text revision

18/12/2017

Mode of use

To be sold and used only upon veterinary prescription not repeatable.