INTEPRITY VETERINARY

2. Qualitative and Quantitative omposition
Avilamycin.....100 g per kg premix
For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Premix

4. Clinical Particulars

4.1 Therapeutic indications
For the treatment and prevention of necrotic enteritis caused by Clostridium perfringens in growing broiler chickens. The presence of the disease in the flock should be established before preventative treatment.

4.2 Posology and method of administration
To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently.

Mixing Directions:
Thoroughly mix 0.15 to 0.30 kg of Inteprity Veterinary per 1000 kg of feed to yield 15 to 30 ppm of avilamycin.

IMPORTANT: Must be thoroughly mixed in broiler chicken feed before use**.**

For better dispersion, it is recommended that Inteprity Veterinary be thoroughly mixed with a small quantity of the feed ingredients (totalling at least 10 kg) prior to the manufacturing of the medicated feed.

Feeding Directions:
Avilamycin should be fed continuously as the sole ration at 15 to 30 ppm for a period of 21 days during the necrotic enteritis risk period, as determined by the veterinarian.

4.3 Contraindications:
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
No withdrawal period is required for broiler chickens when treated according to the label.

Do not use in laying hens.

When handling the product, avoid inhalation, oral exposure, and direct contact with skin or eyes. Use protective clothing, impervious gloves, goggles, and an approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention.

Keep out of reach of children.

4.5 Adverse reactions:
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medical product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

5. Pharmacological Properties

Description:
Avilamycin is an antibiotic of the orthosomycin family produced by fermentation of *Streptomyces viridochromogenes*. Orthosomycin antibiotics are divided into two groups: those that contain an aminocyclitol residue and those that are esters of dichlorisoeverninic acid. Avilamycin falls into the latter group as do the everninomicins.

Avilamycin inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit and preventing the association of translation initiation factor IF2, which inhibits the formation of the mature 70S initiation complex, and the correct positioning of tRNA in the aminoacyl site.

Activity:
Avilamycin is primarily active against Gram-positive bacteria and lacks antimicrobial activity against Gram-negative bacteria (including *Escherichia coli*) as determined by antimicrobial susceptibility testing. The minimal inhibitory concentration (MIC) range for the Gram positive bacteria *Bacillus* spp., *Clostridium* spp., *Corynebacterium bovis*, *Enterococcus* spp., *Lactobacillus* spp., *Listeria monocytogenes*, *Micrococcus luteus*, *Staphylococcus aureus* and *Streptococcus* spp. is 0.0125-1.6 µg/mL.

6. Pharmaceutical Particulars

6.1 List of excipients
Isopar M (Mineral Oil)
Soybean Mill Run

6.2 Incompatibilities

Do not use in feeds containing pellet binding agents with the exception of calcium lignosulfate pellet binder

6.3 Shelf life
The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage
Store below 25°C.

6.5 Nature and contents of container
25 Kg of light to medium brown free flowing preparation in bag constructed from 3-ply kraft paper. The inner paper ply is laminated with polyethylene and aluminium foil and faced with polyethylene.

7. Marketing Authorization holder:
Euromar Ltd. POB 1064 47110 Ramat Hasharon Israel

8. Registration Number:
163 88 35209 00

9. Manufacturer
TriRx Speke Limited, Fleming Road, Speke, Liverpool L24-9LN, United Kingdom

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