

Controlled Medicine
Veterinary Use Only

Savior

Apramycin 10% w/w Premix

1. Brand or Product Name / Name and Strength of Active Substance(s)

Savior Apramycin 10% w/w Premix

Each kg contains Apramycin Sulphate (active substance) equivalent to 100g apramycin activity

2. Product Description : Light yellowish to light brown powder.

3. Pharmacodynamics/Pharmacokinetics/Environmental Properties

Pharmacodynamics :

Apramycin is a broad-spectrum aminocyclitol antibiotic produced by a strain of *Streptomyces tenebrarius*.

Apramycin is bactericidal at minimum inhibitory concentrations.

Apramycin is effective against both Gram-negative and Gram-positive bacteria and some strains mycoplasma at concentrations of 16 µg/mL or less.

It is effective against most field strains of *Escherichia coli* and *salmonella*.

Pharmacokinetics :

The oral administration of apramycin is intended for antimicrobial activity within the gut ; apramycin is poorly absorbed, particularly in older animals.

Absorption : Pigs.

Nine mg of apramycin/kg bodyweight administered orally is well absorbed in 2- day old pigs, slightly absorbed in 4-week old pigs and not absorbed in 8-week old pigs.

Distribution, Biotransformation and Excretion : Pigs.

Very little metabolism of apramycin takes place in the animal. Dosing 10kg pigs with 14C apramycin resulted in approximately 83% being recovered from the faeces, and 4% from the urine, as 14C apramycin.

4. Indication

For the treatment and control of bacterial enteritis caused by *Escherichia coli* and other apramycin sensitive organisms.

5. Recommended Dosage / Mode of Administration

Oral : Mix with animal Feed

Pig : The dose is 4~8 mg kg bodyweight. To achieve this, thoroughly mix 1.0kg of Savior Apramycin Premix in one tonne of finished feed to provide 100 ppm apramycin activity. It is recommended to first thoroughly mix 1 part of product to 20 parts of feed (e.g. 1kg of Savior Apramycin Premix to 20kg feed) before incorporation into the finished feed. Feed as the only ration for a maximum of 28 days or as directed by the veterinary surgeon.

6. Contraindications

- Do not use in cases of known hypersensitivity to apramycin.
- Do not use in cats.

7. Warnings and Precautions

- Read full directions before use.
- Do not exceed the recommended dosage.
- Keep the withdrawal period.
- Put on the protected wears and devices such as gloves and mask in order to client's safety.
- Use by veterinarian's instruction, and veterinary use only.
- Keep out of reach of children/ Jauhi ubat daripada kanak-kanak.

8. Interactions with Other Medicaments

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

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9. Statement on usage during pregnancy and lactation

Savior Premix is not intended for use in pregnant or lactating animals. However, laboratory studies in the rat and rabbit have not produced any evidence of a teratogenic effect.

10. Adverse Effects/Undesirable Effects

If suspected adverse reactions occur, treatment should be discontinued and to inform veterinarian/ local authority.

11. Overdose and Treatment

Stop medication and to seek for veterinarian advice If there is sign of overdosage.

12. Withdrawal Period(s)

Pig - 14 days

13. Storage conditions

Store in a dry and cool place below 30 °C .

Store in well-tight container.

14. Dosage Forms and packaging available

20 kg

15. Name and Address of manufacturer/marketing authorization holder

Nutri Pharmax Sdn Bhd

6, Lorong Serunai 1, Valdor Sungai Bakap, 14200 Sungai Jawi, Pulau Pinang, Malaysia.

16. Date of Revision of Package Insert : 18 MAR 2021

Manufactured by
 **KBNP, INC.**
235-9 Chusaro, Sinam, Yesan,
Chungnam, Korea

Product Registration Holder
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