

Apra 100g/225g Soluble Powder
MALXXXXXXXXHA

ACTIVE INGREDIENT:

Each bottle contains 225 gm Apramycin Sulfate , equivalent to 100 gm apramycin activity

PRODUCT DESCRIPTION:

A brown colour powder

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 of mycoplasma at concentrations of 16 µg/ml or less. It is effective against most field strains of *Escherichia coli* and salmonellae.

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.

Calves. Serum levels peak at approximately 6 hours with a value of 2.4 µg/ml following oral administration of 40 mg apramycin/kg bodyweight. Duration of serum activity is between 24 and 36 hours.

Distribution, Biotransformation and Excretion:

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

INDICATION:

Apra Soluble Powder is indicated for the treatment of bacterial enteritis associated with organisms susceptible to apramycin in pigs, colibacillosis and salmonellosis in calves *Escherichia coli* septicaemia in young chickens. The following organisms were susceptible to Apramycin at concentrations of 16 µg/ml or less: i) Gram-positive bacteria *Staphylococcus aureus* ii) Gram-negative bacteria *Bordetella bronchiseptica*, *Escherichia coli*, *Campylobacter spp*, *Klebsiella spp*, *Salmonella spp*, *Proteus spp*, *Pseudomonas aeruginosa*, *Shigella sonnei*, iii) *Mycoplasma hyopneumoniae*

DOSAGE AND ADMINISTRATION:

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of Apra Soluble Powder has to be adjusted accordingly.

Add the appropriate quantity of the product to 5-10 times its own volume of water. Stir well and allow the solution to stand for a few minutes and then stir again. When completely dissolved, add the full volume of drinking water and stir well.

Pigs:

To be administered via the drinking water. Treated pigs should consume sufficient medicated drinking water to obtain 7.5-12.5 mg apramycin activity per kg of bodyweight daily for seven days.

As a guide, average daily water consumption for fattening pigs is shown in the following table:

Approx. Galls	Average Consumption (liters)	Body Weight (kg)
0.25	1.10	5
0.4	1.75	10

Calves:

To be administered in the drinking water, milk or milk replacer to receive 20-40 mg of apramycin activity per kg of bodyweight daily according to the severity of the disease. Continue treatment for five days. The full dose should be given once daily according to the following table:

Solutions in milk and reconstituted milk replacer should be prepared immediately before use. Any medicated milk or milk replacer which is not consumed within one hour should be discarded.

Apramycin (g)	Apra Soluble 100	Body Weight (kg)
1.0 to 2.0	2.25 – 4.5 gm	50
5.0 to 10	11.26 -- 22.5 gm	250
50.0- 100.0	112.5 – 225 gm	2500

Chickens:

To be administered in the drinking water to receive 250 or 500 mg/liter of apramycin activity for five days. This may be achieved by adding 50g apramycin activity per 100 to 200 liters of water.

Any medicated water which is not consumed within 24 hours should be discarded.

CONTRAINDICATIONS:

Do not use in cases of known hypersensitivity to apramycin.

Do not use in cats.

WARNINGS & PRECAUTIONS:

Avoid inhaling the powder while preparing the medicate water.

Avoid contact with skin and eyes. In the event of skin contact, wash thoroughly with soap and water.

In the event of accidental eye contact, wash the affected eye with fresh running water and seek medical attention if irritation persists.

Wash hands after use.

INTERACTION WITH OTHER MEDICAMENTS:

Drinking systems should be clean and free of rust to avoid reduction of activity.

PREGNANCY AND LACTATION:

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.

More than four times the recommended dose was given to boars prior to and during breeding and to sows after the period of service, during gestation and early lactation. No adverse effects on fertility were seen.

SIDE EFFECTS:

None known.

OVERDOSE AND TREATMENT:**Pigs:**

Pigs have been given up to nine times the recommended use level in their drinking water for 28 days with no untoward reaction.

Calves:

Calves were given Apra Soluble in milk replacer daily for five days, at doses up to 120 mg/kg bodyweight (3-times recommended use level). There was no toxic effect.

Poultry:

There was no mortality when chickens were given a single oral dose of 1000 mg/kg bodyweight. Chickens were given up to 5 times the recommended level for 15 days with no untoward reaction.

WITHDRAWAL PERIOD:

Pigs: 14 days

Calves: 28 days

Chickens: 7 days

Do not use in laying chickens when eggs are intended for human consumption.

STORAGE CONDITION;

Store in cool dry place below 30 °C.

DOSAGE FORMS AND PACKAGING :

225 gm / bottle (plastic container)

12 Bottles / carton

SHELF LIFE:

3 years

Shelf life after opening container – 28 days

Shelf life after dilution in water– 24 hours

Manufactured by

NAM PHARMA SDN BHD

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Taman Perindustrian Antarabangsa IGB

31200, Chemor, Perak , Malaysia

Registered and Distributed by,

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