Veterinary Package Insert

TP-Asperine 900MG/G Powder (90% Sodium Salicylate)

PRODUCT DESCRIPTION
White or almost white colour powder, which contains 900mg of sodium salicylate per gram.

PHARMACODYNAMICS & PHARMACOKINETICS
Sodium salicylate is a non-steroid anti-inflammatory drug (NSAID) and has an anti-inflammatory, analgesic and antipyretic effect. The mode of action is based on inhibition of the enzyme cyclooxygenase, resulting in decreased production of prostaglandin (inflammation mediators).

Orally administered sodium salicylate is rapidly absorbed by passive diffusion, partially from the stomach, but mainly from the anterior part of the small intestine. Sodium salicylate distributes very well to the various tissues. Values of volume of distribution (Vd) are higher in the newborns. Half lives are longer in the very young resulting in slower elimination of the substance. This is most prominent in animals up to 7-14 days of age. Metabolism takes place mainly in the endoplasmatic reticulum and the mitochondria of the liver cells.

Elimination occurs mainly via the urine and the pH of the urine can have a major effect on this elimination.

INDICATION
Pigs: For the treatment of inflammation in combination with concurrent antibiotic therapy.

TARGET SPECIES
Pigs.

RECOMMENDED DOSAGE AND ADMINISTRATION
Pigs: 39mg of product (35 mg sodium salicylate) per kg bodyweight per day, for 3 to 5 days.

To be administered orally in drinking water.

The following formula can be used to calculate the concentration of product in drinking water or milk:

$$\frac{\text{.....mg [product] /kg body weight/day} \times \text{mean body weight (kg) of animals to be treated}}{\text{Mean daily water/milk consumption (l) per animal}} = \text{.... mg [product] per l drinking water / milk}$$

CONTRAINDICATIONS
Do not administer in case of severe hypoproteinaemia, liver and kidney disorder.

Do not administer in case of gastrointestinal ulcerations and chronic gastrointestinal disorders.

Do not administer in case of malfunction of the haemopoietic system, coagulopathy, haemorrhagic diathesis.

Do not use in piglets of less than 4 weeks of age

Do not use in animals with known hypersensitivity to sodium salicylate.

WARNINGS & PRECAUTIONS.
Special precautions for use in animals
Given that sodium salicylate may inhibit clotting of blood, it is recommended that elective surgery should not be performed on animals within 7 days after the end of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to sodium salicylate or related substances (e.g. aspirin) should avoid contact with the veterinary medicinal product.

Irritation of the skin, eye, and respiratory tract might occur. During preparation and mixing of the product, direct contact with the skin and eyes and inhalation of the powder should be avoided. It is recommended to wear gloves, safety glasses, and a dust mask.

In case of accidental dermal exposure wash skin immediately with water. In the event of accidental eye contact, the user is advised to wash the eye with plenty of water for 15 minutes, and seek medical advice if irritation persists. During administration of medicated water or milk (replacer) to the animals skin contact should be prevented by wearing gloves. Wash accidentally exposed skin immediately with water.

INTERACTIONS WITH OTHER MEDICATIONS
Concurrent administration of potentially nephrotoxic drugs (e.g. aminoglycosides) should be avoided.

Salicylic acid is highly plasma (albumin) bound and competes with a variety of compounds (e.g. ketoprofen) for plasma protein binding sites.

Plasma clearance of salicylic acid has been reported to increase in combination with corticosteroids possibly due to induction of metabolism of salicylic acid.

Concurrent use with other NSAIDs is not recommended, because of increased risk of gastro-intestinal ulceration.

Drugs which affect blood clotting should not be used in combination with sodium salicylate.

PREGNANCY AND LACTATION

The use is not recommended during pregnancy and lactation because laboratory studies in rats have shown evidence of teratogenic and foetotoxic effects.

Salicylic acid crosses the placenta and is excreted with the milk. Half-life in the new-born is longer and thus toxicity symptoms may occur much sooner. Furthermore platelet aggregation is inhibited and bleeding time increased which is not favourable during difficult parturition / caesarean section. Finally some studies indicate that parturition is postponed.

ADVERSE EFFECTS

Gastrointestinal irritation may occur especially in animals with pre-existing gastrointestinal disease. Such irritation may be clinically manifested by production of black faeces due to bleeding in the gastrointestinal tract.

Inhibition of normal blood clotting may occur incidentally. This effect is reversible and diminishes within approximately 7 days.

OVERDOSE & TREATMENT

Pigs tolerate dosages up to 175 mg/kg for up to 10 days without any significant adverse effects.

In case of an acute overdose intravenous bicarbonate infusion results in a higher clearance of salicylic acid by alkalisation of the urine and may be beneficial in correcting (secondary metabolic) acidosis.

WITHDRAWAL PERIOD

Meat and offal (pigs): 0 days

MAXIMUM RESIDUAL LIMIT (MRL)

No MRL required.

STORAGE CONDITION

Store below 30°C. Protect from direct sunlight.

SHELF LIFE

2 years.

After 1st opening, reconstitution or dilution, use within 24 hours.

PACKING

100g
500g
1kg

THYE PHARMA SDN. BHD.
(manufacturer & product registration holder)
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