

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Suispirin, 1000 mg/g, oral powder for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1.0 g powder contains:

Active substance:

Acetylsalicylic acid 1000 mg

3 PHARMACEUTICAL FORM

Oral powder.

White to almost white powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

Pig:

Supportive treatment for reduction of pyrexia in combination with, appropriate anti-infective therapy, if necessary.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or in cases of gastrointestinal irritation and ulcers, chronic gastro-intestinal disorders, bronchospasm, liver function impairment or nephropathies.
Do not use in pregnant or lactating sows.
Do not use in piglets less than 4 weeks of age.

4.4 Special warnings for each target species

In combined treatment with tetracyclines, a treatment interval of at least one hour between the two active agents is recommended.

4.5 Special precautions for use

Special precautions for use in animals

It must be ensured that the animals consume sufficient water during treatment.

Given that Suispirin 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

Do not eat, drink or smoke whilst using this product. Contact via the skin or mucous membranes of the user must be avoided due to the risk of sensitisation. If you know that you are allergic to aspirin, avoid contact with this product. Use suitable protective clothing when using this product, such as gloves and a face mask. Wash hands and all exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

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

Inhibition of normal blood clotting may occur incidentally. If this effect occurs it will be reversible and effects will diminish within approximately 7 days.

4.7 Use during pregnancy, lactation or lay

Do not use during the whole of pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Penicillins, sulphonamides

As a result of its high plasma protein binding, acetylsalicylic acid may suppress strongly binding substances such as penicillins and sulphonamides, therefore potentiating their effect.

Furosemide

The diuretic effect of furosemide is decreased. This may cause symptoms of toxicity in animals receiving high aspirin doses.

Tetracyclines

Combined administration of buffered acetylsalicylic acid with tetracyclines may lead to chelate formation.

Amnioglycoside antibiotics

A combination of acetylsalicylic acid and aminoglycoside antibiotics leads to increased nephrotoxic potential.

Ascorbic acid, methionine, ammonium chloride

Urinary acidification caused by ascorbic acid, methionine or ammonium chloride leads to decelerated renal salicylic acid secretion with heightened risk of toxic reactions.

Medicines leading to urinary alkalinisation (sodium hydrogen carbonate)

The renal secretion of salicylic acid is accelerated by the alkalinisation of the urine (sodium hydrogen carbonate).

Non-steroid anti-inflammatories

Combination with other NSAIDs leads to increased or intensified occurrence of side effects, particularly within the gastro-intestinal tract.

Glucocorticoids

Simultaneous administration of glucocorticoids increases the risk of gastro-intestinal bleeding.

4.9 Amounts to be administered and administration route

Oral powder for top dressing use.
For use in individual pigs on farms where only a small number of pigs are to receive the veterinary medicinal product.
Pig:
30 mg acetylsalicylic acid (corresponding to 30 mg of the product) per kg BW twice daily.

The treatment period is 3 consecutive days.
Minimum body weight of pigs to be treated: 11 kg.
Treatment is achieved by mixing the product with approximately 50 g or 200 g (according to bodyweight) of the normal diet per pig. For measuring the correct amount of the veterinary medicinal product please use the enclosed scoops according to the dosage table below. Non-medicated feed should only be offered after complete consumption of all the medicated feed. Animals should be isolated from other animals for treatment.
Medicated feed should be freshly prepared before each administration.

| Pig Type | Bodyweight (kg) | Grams of the product per animal (Twice daily) | Equal amount in ml (for measuring the dose with scoops) |
|-----------------------|-----------------|---|---|
| Weaner pig (small) | 11 | 0.33 | 0.4 |
| Weaner pig (big) | 25 | 0. 75 | 1.0 |
| Fattening pig (small) | 50 | 1.50 | 2.0 |
| Fattening pig (big) | 100 | 3.00 | 4.0 |
| Sow | 250 | 7.50 | 10.0 |

Scoops – two scoops measuring 0.4 ml (= 0.33 g of the product) and 3 ml (= 2.25 g of the product) are supplied.

Part-consumed feed must be disposed of with other waste feed and not given to other animals.
To avoid overdosing the pigs to be treated should be weighed or body weight accurately estimated by an experienced person.
Feed consumption may be reduced in clinically sick animals and also in older pigs therefore feed intake may need to be adjusted to achieve target dosage intake. The correct quantity of the product should be thoroughly mixed with the feed in a bucket or similar receptacle. To achieve good mixture and homogeneity a pre-mixture can be used.
The product should only be added to dry non-pelleted feed. Do not in use in a dry hopper or a semi liquid feeder.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Pigs tolerate dosages up to 90 mg/kg for up to 6 days without any significant adverse effects.
Treatment in case of overdose: discontinue treatment with acetylsalicylic acid immediately and initiate symptomatic treatment. The alkalinisation of the urine with sodium hydrogen carbonate may lead to accelerated secretion of acetylsalicylic acid or salicylic acid.

4.11 Withdrawal Period(s)

Pig:
Meat and offal: 1 day

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other analgesics and antipyretics, Salicylic acid and derivatives
ATCvet code: QN02BA01

5.1 Pharmacodynamic properties

Acetylsalicylic acid is a well-known, non-steroidal anti-inflammatory and one of the weak analgesics. Acetylsalicylic acid has an anti-inflammatory effect, a peripheral analgesic and antipyretic effect and it inhibits thrombocyte aggregation.

The effectiveness of acetylsalicylic acid is due primarily to the inhibition of the enzyme cyclooxygenase, responsible for the formation of prostaglandins and thromboxane from arachidonic acid. Prostaglandins are significant causes of inflammations, pain and fever.

5.2 Pharmacokinetic properties

Following oral administration, acetylsalicylic acid is absorbed in the stomach and upper small intestine depending on the stomach contents, its pH value and evacuation time as well as the galenic formulation. It is hydrolysed to its main metabolite salicylic acid within only a few minutes. Deacetylation begins with the absorption into the mucosa and takes place to a large extent during first pass metabolism. Particularly high concentrations of the main metabolite, salicylic acid, can be found in the stomach wall, liver, heart, lungs, renal cortex, blood plasma, bone marrow and inflamed tissue. Relatively low concentrations are observed in non-inflamed muscle, fat and connective tissue. Following administration of acetylsalicylic acid to pigs, maximum plasma concentrations of salicylic acid are reached approximately 2 to 3 hours post administration via the feed. 24 hours after the final application, only traces of salicylic acid can be detected in the plasma and tissue.

The distribution volume of salicylic acid is low. Up to 75% of salicylic acid is bound to plasma proteins in pigs. Salicylate may overcome the placental barrier.

The elimination half life increases with increasing acetylsalicylic acid doses. The mean terminal half life for salicylic acid after treatment with the product via the feed was found to be between 1.8 and 3.7 hours.

Following conjugation in the liver, salicylic acid is secreted via the kidneys. Secretion is accelerated with urine pH values between 5 and 8.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

In absence of compatibility study this product cannot be mixed with other veterinary products.

6.3 Shelf-life

| | |
|--|----------|
| Shelf-life of the veterinary medicinal product as packaged for sale: | 5 years |
| Shelf-life after first opening the immediate packaging : | 6 months |
| Shelf-life after addition to the feed according to directions: | 15 hours |

6.4 Special precautions for storage

Securely reclose part-used containers or sachets after use.

6.5 Nature and composition of immediate packaging

1 x 100 g powder and 10 x 100 g powder are filled in sachets with paper / polyethylene / aluminium / polyethylene foil. Polystyrene scoops of 0.4 ml and 3 ml are attached.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10826/013/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th October 2011

10 DATE OF REVISION OF THE TEXT