<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Label}{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suispirin, 1000 mg/g, oral powder for pigs
Acetylsalicylic acid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g powder contains:

Active substance:
Acetylsalicylic acid 1000 mg

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

100 g
10 x 100 g

5. TARGET SPECIES

Pig

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral powder for top dressing use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pig:
Meat and offal: 1 day

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging : 6 months
Shelf-life after addition to the feed according to directions: 15 hours
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Securely reclose part-used containers after use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: see package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Distributor
Same as MAH

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4013

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PACKAGE LEAFLET FOR:
Suispirin, 1000 mg/g, oral powder for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
Esplugues de Llobregat
08950 Barcelona
Spain

Distributor
Same as MAH

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suispirin, 1000 mg/g, oral powder for pigs
Acetylsalicylic acid

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 g powder contains:

Active substance:
Acetylsalicylic acid 1000 mg

White to almost white powder.

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 Suispirin 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 kg	0.33 g	0.4 ml
Weaner pig (big)	25 kg	0. 75 g	1.0 ml
Fattening pig (small)	50 kg	1.50 g	2.0 ml
Fattening pig (big)	100 kg	3.00 g	4.0 ml
Sow	250 kg	7.50 g	10.0 ml

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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Pig:
Meat and offal: 1 day

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use after the expiry date listed on the sachets and outer cartons after “EXP”. The expiry date refers to the last day of that month.
Securely reclose part-used containers or sachets after use.

Shelf-life after first opening the immediate packaging : 6 months
Shelf-life after addition to the feed according to directions: 15 hours

12. SPECIAL WARNING(S)

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

Special precautions for use in animals

It must be ensured that the animals consume sufficient water during treatment.
Given that the veterinary medicinal product 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.

Use during pregnancy, lactation or lay

Do not use during the whole period of pregnancy and lactation.

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.

Aminoglycoside 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-steroidal 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.

Overdose (symptoms, emergency procedures, antidotes)

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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.
For animal treatment only. To be supplied only on veterinary prescription.

Approved: 20 October 2016