MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {BAG/100 g, 250 g, 500 g, 1.0 kg, 2.5 kg and 5.0 kg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solacyl 1000 mg/g powder for use in drinking water/milk for cattle and pigs

2. COMPOSITION

Each gram contains:

Active substance:
Sodium salicylate 1000 mg, corresponding to 862.6 mg of salicylic acid (as sodium salt).
Powder for use in drinking water/milk
White to off-white flakes.

3. PACKAGE SIZE

100 g, 250 g, 500 g, 1.0 kg, 2.5 kg and 5.0 kg.

4. TARGET SPECIES

Cattle (calves) and pigs.

5. INDICATIONS FOR USE

Calves: supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g. anti-infective) therapy if necessary.

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

6. CONTRAINDICATIONS

Do not administer in case of severe hypoproteinemia, 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, hemorrhagic diathesis.
Do not use sodium salicylates in neonates or calves less than 2 weeks of age.
Do not use in piglets of less than 4 weeks of age.
Do not use in cases of hypersensitivity to the active substance.

7. SPECIAL WARNINGS

Special precautions for safe use in the target species:
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 veterinary medicinal 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.

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.

Interactions with other medicinal products and other forms of interaction:
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 non-steroid anti-inflammatory drugs (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.

Overdose:
Calves tolerate dosages up to 80 mg/kg for 5 days or 40 mg/kg for 10 days without any adverse effects. 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.

Major incompatibilities:
In the absence of compatibility studies, the veterinary medicinal product must not be mixed with other veterinary medicinal products. The veterinary medicinal product can be administered as pulse medication (3-4 hours) twice daily so that if it is to be used in combination with other medications, these can be given separately.

8. ADVERSE REACTIONS

Cattle (Calves) and pigs:

Undetermined frequency (cannot be estimated on the available data)	Gastrointestinal irritation[a] (Tarry or black stool[b]), Prolonged bleeding[c]

[a] especially in animals with pre-existing gastrointestinal disease.
[b] due to bleeding in the gastrointestinal tract.
[c] inhibition of normal blood clotting may occur incidentally. This effect is reversible and diminishes within approximately 7 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

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

In drinking water/milk use.

Calves: 40 mg sodium salicylate per kg bodyweight once daily, for 1 to 3 days.
Administration: orally in drinking water or milk(replacer).

Pigs: 35 mg sodium salicylate per kg bodyweight per day, for 3 to 5 days.
Administration: orally in drinking water.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{.....mg veterinary medicinal product /kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water/milk consumption (l/animal)}} = \text{.... mg veterinary medicinal product per litre of drinking water/milk}$$

Alternatively the veterinary medicinal product can also be administered with the drinking water as pulse medication. Half of the calculated total daily amount of powder is mixed with 5-10 litres of clean water and stirred until evenly dispersed. This solution is then added, whilst stirring, into an amount of drinking water that will be consumed within approximately 3-4 hours and administered twice daily.

Maximum solubility of the veterinary medicinal product in water is approximately 100 g/litre.

10. ADVICE ON CORRECT ADMINISTRATION

The use of suitably calibrated weighing equipment for the administration of the calculated amount of sodium salicylate is recommended.

11. WITHDRAWAL PERIOD

Meat and offal:
Pigs: zero days.
Calves: zero days.
Do not use in animals producing milk for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Keep the bag tightly closed after first opening in order to protect from moisture and light.
This veterinary medicinal product does not require any special temperature storage conditions.

When the bag is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded. This discard date should be written in the space provided.

Shelf life after first opening the immediate packaging: 6 months.
Shelf-life after dissolution in drinking water according to directions: 24 hours.
Shelf-life after dissolution in milk (replacer) according to directions: 6 hours.
After this period, remaining unused solution should be discarded.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 16849/5004

Pack sizes are 100 g, 250 g, 500 g, 1.0 kg, 2.5 kg and 5.0 kg.

Sachet with an outer layer of polyethylene terephthalic acid, middle layers of polyethylene and aluminium and an inner layer of polyethylene (PET/PE/ALU/PE).

Sachet with an outer layer of polyester, middle layers of polyethylene and aluminium and an inner layer of surlyn-ionomer (PO/PE/ALU/Ionomer).

Sachet with an outer layer of polyethylene terephthalic acid, middle layers of aluminium and polyamide and an inner layer of polyethylene (PET/ALU/PA/PE).

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

September 2023

Find more product information by searching for the Product Information Database ‘PID’ on www.gov.uk.

17. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands
Tel: +44 (0)1939 211200

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

EXP: {mm/yyyy}

Once opened, use by: __/__/____

Do not use this veterinary medicinal product after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

21. BATCH NUMBER

Lot: {number}

22. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

Approved 22 September 2023