PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{BAG/100 G, 250 G, 500 G, 1 KG, 2,5 KG and 5 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, equivalent to 862,6 mg of salicylic acid (sodium salt).
Powder for use in drinking water/milk.
White to off-white flakes.

3. PACKAGE SIZE

100 g, 250 g, 500 g, 1 kg, 2,5 kg and 5 kg.

4. TARGET SPECIES

Cattle (calves) and pigs.

5. INDICATIONS FOR USE

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

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 haematopoietic system, coagulopathy, haemorrhagic 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 warnings

Special warnings:
None known.

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. Personal protective equipment consisting of gloves, safety glasses, and a dust mask should be worn when handling the veterinary medicinal product.
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.

Special restrictions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation, because laboratory studies in rats have shown evidence of teratogenic and fetotoxic 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.

Interaction 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-steroidal 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.

Special precautions for use and special conditions for use:
Not applicable.

Major incompatibilities:
In the absence of compatibility studies, this 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 EVENTS

Adverse events

Cattle (calves) and pigs:

Undetermined frequency (cannot be estimated from the available data)	Gastrointestinal irritation[a] (tarry or black stool[a+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 veterinary medicinal product. If you notice any side effects, even those not already listed on this label, 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 on this label, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water/milk use.
Calves: 40 mg sodium salicylate per kg bodyweight once daily, for 1 to 3 consecutive days.
Administration: orally in drinking water or milk(replacer).
Pigs: 35 mg sodium salicylate per kg bodyweight per day, for 3 to 5 consecutive 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:

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

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

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 PERIODS

Withdrawal periods

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

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 16849/3004

Pack sizes

100 g, 250 g, 500 g, 1 kg, 2,5 kg and 5 kg

Sachet/bag with outside to inside layers of white polyethylene terephthalate, polyethylene, aluminium, polyethylene (PET/PE/ALU/PE).

Sachet/bag with outside to inside layers of polyester, polyethylene, aluminium, ionomer (PO/PE/ALU/Ionomer).

Sachet/bag with outside to inside layers of polyethylene terephthalate, aluminium, polyamide, polyethylene (PET/ALU/PA/PE).

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions
Eurovet Animal Health BV
Handelsweg 25
5531-AE Bladel
The Netherlands
Tel: +44 (0) 1939 211200

Local representatives and contact details to report suspected adverse reactions

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

Other information

POM-V Prescription Only Medicine – Veterinarians

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened, use by: __/__/__
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.

21. BATCH NUMBER

Lot {number}

Approved 22 September 2023