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

{BAG/100 G, 250G, 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 for turkeys

2. COMPOSITION

Each gram contains:
Sodium salicylate 1000 mg, equivalent to 862,6 mg of salicylic acid (as sodium salt)
Powder for use in drinking water.
White to off-white flakes.

3. PACKAGE SIZE

100 g, 250 g, 500 g, 1 kg, 2.5 kg, 5 kg

4. TARGET SPECIES

Turkeys.

5. INDICATIONS FOR USE

Indications for use

Symptomatic treatment of inflammatory respiratory diseases, if necessary in combination with an appropriate anti-infective therapy.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to the active substance.
Do not use in case of severe liver and kidney disorders.
Do not use in case of gastrointestinal ulcerations and chronic gastrointestinal disorders.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
The compatibility of the veterinary medicinal product with other veterinary medicinal products when administered via the drinking water has not been investigated. If used concurrently, the stability and/or solubility of the veterinary medicinal products may change. Therefore, it is recommended that methods or routes of administration other than via drinking water are used to deliver concurrent anti-infective therapy, if needed.

Special precautions for safe use in the target species:

Diseased animals may show altered intake of drinking water or feed. In cases of altered drinking water intake, the concentration of the veterinary medicinal product has to be adjusted to ensure the intake of the required dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

- People with known hypersensitivity (allergies) to sodium salicylate or related substances (e.g. aspirin) should avoid contact with the veterinary medicinal product.
- Irritation of the skin, eyes, and respiratory tract may occur in the case of accidental contact. Direct contact of the skin and eyes with the medicated water or the powder, and inhalation of the powder should be avoided. It is recommended to wear protective gloves (e.g. rubber or latex), safety glasses, and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149). Swelling of the face, lips or eyes or difficulty in breathing are serious symptoms that require immediate medical attention.
- In case of accidental dermal exposure, wash skin immediately with water.
- In the event of accidental eye contact, wash the eye with plenty of water for 15 minutes. If irritation persists, seek medical advice and show the label to the physician.

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

Laying birds:
Laboratory studies in rats have shown evidence of teratogenic and foetotoxic effects. The use is not recommended during lay.

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. sulphonamides, ketoprofen) for plasma protein binding sites.
Concurrent use with other non-steroidal anti-inflammatory drugs (NSAIDs) is not recommended, because of increased risk of gastro-intestinal disturbances.

Overdose:
The administration of four times the recommended dose resulted in an increase in drinking water consumption and occasional diarrhoea.

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.

8. ADVERSE EVENTS

Adverse events

Turkeys:

Undetermined frequency (cannot be estimated from the available data)	Gastrointestinal irritation[a] (Tarry or black stool[a+b)], Drinking a lot[c]

[a] especially in animals with pre-existing gastrointestinal disease.
[b] due to bleeding in the gastrointestinal tract.
[c] Increase in water intake.

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 use.
86,2 mg salicylic acid/kg bodyweight daily (equivalent to 100 mg product/kg body weight daily) for 3 consecutive days.

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:

$$\frac{\text{100 mg veterinary medicinal product/kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{.... mg veterinary medicinal product per litre of drinking water}$$

The maximum solubility of the product in drinking water is approximately 100 g/litre.
Medicated drinking water should be freshly prepared every 24 hours.
Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being on treatment.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

For weighing the calculated amount of sodium salicylate the use of suitably calibrated weighing equipment is recommended.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 2 days.
Not for use in birds producing or intended to produce eggs 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

MA number: Vm 16849/3003.

Pack sizes
100 g, 250 g, 500 g, 1 kg, 2.5 kg and 5 kg
Bags consisting of the following materials: an outer layer of polyethylene terephthalic acid, inside layers of aluminium and polyamide and an inner layer of polyethylene

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

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.

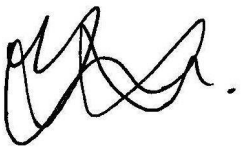
20. EXPIRY DATE

Exp: {mm/yyyy}
Shelf-life after first opening the immediate packaging: 6 months.
Once opened use by: __/__/__

Shelf life after dissolution according to directions: 24 hours.
After this period, remaining unused solution should be discarded.

21. BATCH NUMBER

Lot {number}



Approved: 20 September 2023