SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solacyl 1000 mg/g powder for use in drinking water for turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

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. CLINICAL INFORMATION

3.1 Target species

Turkeys.

3.2 Indications for use for each target species

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

3.3 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.

3.4 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.

3.5 Special precautions for use

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.

3.6 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. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the combined label-leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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 drug (NSAIDs) is not recommended, because of increased risk of gastro-intestinal disturbances.

3.9 Administration routes and dosage

In drinking water use.
86,2 mg salicylic acid/kg bodyweight daily (equivalent to100 mg veterinary medicinal 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 veterinary medicinal product in drinking water is approximately 100 g/litre.
For weighing the calculated amount of sodium salicylate the use of suitably calibrated weighing equipment is recommended.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN02BA04

4.2 Pharmacodynamics

Sodium salicylate is a non-steroidal anti-inflammatory drug (NSAID) and has an anti-inflammatory effect. The mode of action is based on inhibition of the enzyme cyclooxygenase, resulting in decreased production of prostaglandin (inflammation mediators).

4.3 Pharmacokinetics

In turkeys, orally administered sodium salicylate is absorbed by passive diffusion partially from the stomach and mainly from the small intestine. The passage through the crop influences the absorption rate and initial sodium salicylate plasma levels depend on how full the crop is. After administration into the crop maximum plasma concentrations are reached in approximately three hours (average), $t_{1/2}$ is approximately two hours. When dosed orally via the drinking water (dose of 100 mg/kg body weight per day for three days) average plasma concentrations above 20 µg/ml are achieved.

Sodium salicylate distributes very well to the various tissues; the highest concentrations are reached in the liver, kidneys and lungs. Accumulation in inflammatory exudate could be detected. Further studies on metabolism are not available for the turkey. Excretion is probably primarily renal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dissolution according to directions: 24 hours.
After this period, remaining unused solution should be discarded.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

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.
Pack sizes are 100 g, 250 g, 500 g, 1 kg, 2.5 kg and 5 kg.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 16849/3003

8. DATE OF FIRST AUTHORISATION

05 October 2017

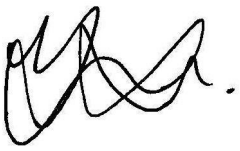
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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



Approved: 20 September 2023