

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 g contains:

Active substance:

Sodium salicylate 1000 mg, corresponding to 862.6 mg of salicylic acid (as sodium salt)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
White to off-white flakes.

4. CLINICAL PARTICULARS

4.1 Target species

Turkeys.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals:

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, and seek medical advice if irritation persists and show the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Turkeys:

Undetermined frequency (cannot be estimated from the available data)	Gastrointestinal irritation ^a (Tarry or black stool ^b) Drinking a lot ^c
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^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 also the last section of the package leaflet for contact details.

4.7 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.

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

4.9 Amount(s) to be administered and administration route

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:

$$\frac{100 \text{ mg veterinary medicinal product/kg body weight/day}}{\text{average daily water consumption (l/animal)}} \times \frac{\text{average body weight (kg) of animals to be treated}}{1} = \dots \text{ mg veterinary medicinal product per litre of drinking water}$$

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Meat and offal: 2 days.

Not for use in birds producing or intended to produce eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: sodium salicylate

ATC Vet Code: QN02BA04

5.1 Pharmacodynamic properties

Sodium salicylate is a 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).

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Major Incompatibilities

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

6.3 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 reconstitution in drinking water according to directions: 24 hours.
After this period, remaining unused solution should be discarded.

6.4 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.

6.5 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 (PET/ALU/PA/PE).

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

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 16849/5003

9. DATE OF FIRST AUTHORISATION

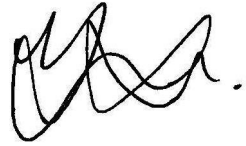
05 October 2017

10. DATE OF REVISION OF THE TEXT

September 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 20 September 2023