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 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 known 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

Gastrointestinal irritation may occur especially in animals with pre-existing gastrointestinal disease. Such irritation may clinically manifest as production of black faeces due to bleeding in the gastrointestinal tract.
The administration of the veterinary medicinal product can lead to an increase in water intake.

4.7 Use during pregnancy, lactation or lay

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

4.8 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. sulfonamides, ketoprofen) for plasma protein binding sites.
Concurrent use with other NSAIDs is not recommended, because of increased risk of gastro-intestinal disturbances.

4.9 Amounts to be administered and administration route

In drinking water use.
86,2 mg salicylic acid/kg bodyweight daily (equivalent to100 mg product/kg body weight daily) for 3 consecutive days

The following formula can be used to calculate the concentration of the veterinary medicinal product in drinking water:

$$\frac{\text{100 mg product/kg body weight/day} \times \text{mean body weight (kg) of animals to be treated}}{\text{Mean daily water consumption (l) per animal}} = \text{.... mg product per l drinking water}$$

The maximum solubility of the 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: Nervous system, analgesics and antipyretics, salicylic acid and derivatives
ATCvet code: QN02BA04

5.1 Pharmacodynamic properties

Sodium salicylate is a non-steroid 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).

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.

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.
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 16849/4058

9. DATE OF FIRST AUTHORISATION

05 October 2017

10. DATE OF REVISION OF THE TEXT

July 2022

Approved 12 July 2022