Part IB-2

LABELLING

SOLACYL 1000 MG/G, POWDER FOR USE IN DRINKING WATER FOR TURKEYS

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 and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

2. Name of the veterinary medicinal product

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

3. Statement of the active substance (s) and other ingredients

Each g contains:
Sodium salicylate 1000 mg, corresponding to 862,6 mg salicylic acid (as sodium salt)

White to off-white flakes.

4. Pharmaceutical form

Powder for use in drinking water

5. Package size

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

6. Indications

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

7. 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.

8. Adverse reactions

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.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

9. Target species

Turkeys.

10. Dosage for each species, route 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.

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.

11. Advice on correct administration

12. Withdrawal period

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

13. Special storage precautions

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.
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.

14. Special warnings

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.

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.

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
The administration of four times the recommended dose resulted in an increase in drinking water consumption and occasional diarrhoea.

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

15. Special precautions for the disposal of unused product or waste materials, if any

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

16. Date on which the label was last approved

June 2022

17. Other information

100 g, 250 g, 500 g, 1 kg, 2.5 kg and 5 kg
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. The words “For animal treatment only” and conditions or restrictions regarding supply and use, if applicable

For animal treatment only.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

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

21. Marketing authorisation number

Vm 16849/4058

22. Manufacturer's batch number

Lot:

Approved 12 July 2022