1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOPHACYL 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, corresponding to 863 mg salicylic acid

White or almost white crystalline powder.

3. CLINICAL INFORMATION

3.1 Target species

Turkeys.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.
Do not use in cases of severe liver and kidney disorders.
Do not use in cases of gastrointestinal ulcerations and chronic gastrointestinal disorders.
Do not use in cases of malfunction of the hematopoietic system, coagulopathies, haemorrhagic diathesis.

3.4 Special warnings

The concentration of the administered solution must be adjusted daily to the actual drinking water consumption of the animals.
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. acetylsalicylic acid) should avoid contact with the product.
Irritation of the skin, eyes and respiratory tract may occur. Direct contact with the skin and eyes and inhalation of the powder should be avoided.

Personal protective equipment consisting of gloves (e.g. rubber or latex), safety glasses and an appropriate single-use respiratory filtering half-mask (e.g. disposable respirator conforming to European Standard EN149) should be worn when handling the veterinary medicinal product.
In the event of accidental eye contact, the user is advised to wash the eye with plenty of water for 15 minutes; seek medical advice if irritation persists. Swelling of the face, lips or eyes or difficulty in breathing are serious symptoms that require immediate medical attention.
During administration of medicated water to the animals skin contact should be prevented by wearing gloves. In case of accidental dermal exposure, wash exposed skin immediately with water.

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[1], black stool[2] Increased drinking

[1]especially in animals with pre-existing gastrointestinal disease.
[2]due to bleeding in the gastrointestinal tract.

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 package leaflet or label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
The use of the veterinary medicinal product is not recommended during lay, since laboratory studies in rats have shown evidence of teratogenic and foetotoxic effects.

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. sulfonamides, 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.

3.9 Administration routes and dosage

In drinking water use.
86.3 mg salicylic acid (100 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:

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

The maximum solubility of the veterinary medicinal product in (soft/hard) water (at 4°C/20°C) is 250 g/litre.
For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.
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 replaced by freshly prepared medicated drinking water.
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 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), t1/2 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 of the immediate packaging: 3 months.
Shelf life after dissolution according to directions: 24 hours.

5.3 Special precautions for storage

Store in the original container in order to protect from light.
Store below 25 °C after first opening of the immediate packaging.
The medicated drinking water should be protected from light.

5.4 Nature and composition of immediate packaging

- Securitainer: white cylindrical polypropylene container, covered with a low-density polyethylene lid.
The securitainer contains 500 g or 1 kg of product.
- Bucket: white polypropylene square container provided with a polypropylene lid.
The bucket contains 1, 2.5 or 5 kg of product.

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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10791/018/001

8. DATE OF FIRST AUTHORISATION

24/06/2022

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

20/12/2024

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).