## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dophacyl Avi, 1000 mg/g powder for use in drinking water for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

**Active substances:**
Sodium salicylate: 1000 mg
(equivalent to 863 mg of salicylic acid)

**Excipients:**
None.

White or almost-white powder.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens.

### 3.2 Indications for use for each target species

Symptomatic treatment of febrile conditions and mild to moderate pain.

### 3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.
Do not use in animals with gastrointestinal ulcers.
Do not use when there is a risk of bleeding.

### 3.4 Special warnings for each target species

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity (allergies) to sodium salicylate or related substances (e.g. aspirin) should avoid contact with the veterinary medicinal product.
If, after accidental contact rash develops, seek medical advice and show the package leaflet or label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms that require urgent medical attention.

This veterinary medicinal product may cause irritation of the skin, eyes and respiratory tract. Direct contact with the skin and eyes, and inhalation of the powder should be avoided.

Personal protective equipment consisting of 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) should be worn when handling the veterinary medicinal product.

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.

Wash hands after use.
Do not smoke, eat or drink while handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chickens:

| | |
|---|---|
| Undetermined frequency (cannot be estimated from the available data): | Prolonged bleeding |

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 immediate packaging 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

Do not use in combination with drugs known to have anticoagulant properties.
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.

The recommended dose is 40 mg sodium salicylate per kg of body weight per day, i.e. 34.5 mg of salicylic acid per kg of body weight per day, for 2 - 3 days.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of sodium salicylate may need to be adjusted accordingly.
The use of suitably calibrated measuring equipment is recommended.

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:

$$\frac{\text{40 mg veterinary medicinal product/ kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{mg veterinary medicinal product per litre of drinking water}$$

The maximum solubility of the product in water (soft/hard) at 4ºC/20ºC is 250 g /L.
The use of a magnetic stirrer is recommended and dissolution can take up to 3 minutes.
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 setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated. Medicated drinking water should be freshly prepared every 24 hours.
Water uptake should be monitored at frequent intervals during medication. The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated drinking water which is not consumed within 24 hours should be discarded.
No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products.

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

The administration of ten times the recommended dose during 3 times the recommended maximum duration of use was well tolerated.

### 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 eggs for human consumption.
Do not use within 2 weeks of the start of the laying period.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet-code: QN02BA04

### 4.2 Pharmacodynamics

Sodium salicylate is a non-steriod anti-inflammatory drug (NSAID) and exerts an anti-inflammatory, analgesic and anti-pyretic effect. The effects are linked to the inhibition of the enzyme cyclo-oxygenase by which the synthesis of prostaglandin (mediator for inflammation) decreases.

### 4.3 Pharmacokinetics

Orally ingested salicylates are absorbed rapidly by passive diffusion, partly from the stomach but mostly from the upper small intestine.
After oral administration of sodium salicylate at a dose of 40 mg/kg bodyweight, the time to reach the maximum concentration ($C_{max}$) of 88.21 µg salicylic acid/mL was 0.9 hours (with a range between 0.38 and 3.07 hours), and the elimination half-life was 2.9 hours.
Salicylic acid is largely bound to plasma proteins. Salicylate is distributed throughout most body tissues. Its metabolism takes mainly place in hepatic endoplasmic reticulum and mitochondria.
Excretion is mainly via the urine and is a pH-dependent process. With a low pH of the urine and poor kidney function, the half-life is prolonged.

## 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:
- Securitainer and bucket: 3 years.
- Sachet: 9 months

Shelf life after first opening the immediate packaging:
- Securitainer and bucket: 3 months.
- Sachet: use immediately.

Shelf life after dissolution according to directions: 24 hours.

### 5.3 Special precautions for storage

Securitainer and bucket: This veterinary medicinal product does not require any special temperature storage conditions.
Sachet: Do not store above 30°C.
Store in the original container in order to protect from light.
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.
- Sachet: white, heat sealed, 4-layer sachet with a PE inner layer which contains 100 g 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)

VPA10791/023/001

## 8. DATE OF FIRST AUTHORISATION

11/10/2024

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

12/09/2025

## 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).