ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOPHACYL T 1000 mg/g powder for use in drinking water for turkeys (AT, DE, HR, HU, IT, NL, PL, RO)
DOPHACYL T powder for use in drinking water for turkeys (FR)
DOPHACYL-Turkey 1000 mg/g powder for use in drinking water for turkeys (ES, PT)
DOPHACYL 1000 mg/g powder for use in drinking water for turkeys (IE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Sodium salicylate 1000 mg, corresponding to 863 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 or almost-white crystalline powder.

4. CLINICAL PARTICULARS

4.1 Target species

Turkeys.

4.2 Indications for use, specifying the target species

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

4.3 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 administer in cases of malfunction of the hematopoietic system, coagulopathies, haemorrhagic diathesis.

4.4 Special warnings for each target species

The concentration of the administered solution must be adjusted daily to the actual drinking water consumption of the animals.
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. 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.
It is recommended to wear protective 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).
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.

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

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.

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.
86.3 mg salicylic acid (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:

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

The maximum solubility of the 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.

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 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), 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.

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 of the immediate packaging: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.

6.4. 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.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

To be completed nationally

8. MARKETING AUTHORISATION NUMBER

To be completed nationally

9. DATE OF THE FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be completed nationally

10. DATE OF REVISION OF THE TEXT

To be completed nationally

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
COMBINED LABEL AND PACKAGE LEAFLET
Securitainer and bucket

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

Marketing authorisation holder:

To be completed nationally

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer, NL

2. Name of the veterinary medicinal product

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

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

Sodium salicylate 1000 mg/g
corresponding to 863 mg salicylic acid (as sodium salt)

4. Pharmaceutical form

Powder for use in drinking water

White or almost-white crystalline powder

5. Package size

500 g, 1 kg, 2.5 kg, 5 kg.

6. Indication(s)

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

7. 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 administer in cases of malfunction of the hematopoietic system, coagulopathies, haemorrhagic diathesis.

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 label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Turkeys.

10. Dosage for each species, route(s) and method of administration

In drinking water use.

86.3 mg salicylic acid (100 mg product)/kg body weight daily, for 3 consecutive days.

11. Advice on correct administration

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

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

The maximum solubility of the 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.

12. Withdrawal period(s)

Withdrawal period(s):
Meat and offal: 2 days.
Not for use in birds producing eggs for human consumption.

13. Special storage precautions

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

14. Special warning(s)

Special warnings for each target species
The concentration of the administered solution must be adjusted daily to the actual drinking water consumption of the animals.
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
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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.

Lay
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..

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
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 products 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 package leaflet was last approved

17. Other information

List of pack sizes:
- Securitainer: 500 g, 1 kg.
- Bucket: 1, 2.5, 5 kg.

Not all pack sizes may be marketed.

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

For animal treatment only - To be supplied only on veterinary prescription.

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 container: 3 months.
Shelf life after dilution according to directions: 24 hours.

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Lot << >>