ANNEX III:

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

- Composite can
- Securitainer
- Bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SODIUM SALICYL 800 mg/g, powder for oral solution for cattle (calves) and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Sodium salicylate 800 mg/g
(equivalent to 690 mg of salicylic acid as sodium salt)

3. PHARMACEUTICAL FORM

Powder for oral solution.

4. PACKAGE SIZE

1, 2.5 or 5 kg.

5. TARGET SPECIES

Cattle (calves) and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use, after dissolution in drinking water/milk replacer.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Calves and pigs:
Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP <<EXP month/year>>

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: 4 hours.

Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

Store below 25 ºC.
Do not refrigerate or freeze.
Protect from frost.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. 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.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 28365/4001

17. MANUFACTURER'S BATCH NUMBER

Batch <<partijnummer>>

B. PACKAGE LEAFLET

PACKAGE LEAFLET

SODIUM SALICYL 80% WSP, powder for oral solution for cattle (calves) and pigs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer The Netherlands

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SODIUM SALICYL 800 mg/g, powder for oral solution for cattle (calves) and pigs.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:

Sodium salicylate 800 mg/g
(equivalent to 690 mg of salicylic acid as sodium salt)

White or almost-white powder.

4. INDICATION(S)

Calves:
For supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (anti-infective) therapy if necessary.
Pigs:
For the treatment of inflammation, in combination with concurrent antibiotic therapy.

5. CONTRAINDICATIONS

Do not administer to animals with severe hypoproteinaemia, liver and kidney affections.
Do not administer in case of gastrointestinal ulcerations and chronic gastrointestinal disorders.
Do not administer in case of malfunction of the hematopoetic system, coagulopathies, haemorrhagic diathesis.
Do not use sodium salicylates in neonates or calves less than 2 weeks of age.
Do not use in piglets less than 4 weeks of age.
Do not use in cases of hypersensitivity to sodium salicylate or to the excipient.

6. ADVERSE REACTIONS

Gastrointestinal irritation may occur especially in animals with pre-existing gastrointestinal disease. Such irritation may clinically be manifested by production of black manure due to blood loss in the gastrointestinal tract.

Inhibition of normal blood clotting may occur incidentally. If this effect occurs it will be reversible and effects will diminish within approximately 7 days.

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.

7. TARGET SPECIES

Cattle (calves) and pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD(S) OF ADMINISTRATION

Calves: 40 mg sodium salicylate per kg of bodyweight once daily,
(equivalent to 50 mg product per kg BW per day),
for 1 - 3 days.
Pigs: 35 mg sodium salicylate per kg of bodyweight per day,
(equivalent to 43.75 mg product per kg BW per day),
for 3-5 days.

The product can be administered orally through the milk-replacer and/or the drinking water.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Calves and pigs:
Meat and offal: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store below 25ºC.
Do not refrigerate or freeze.
Protect from frost.

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: 4 hours.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Given that sodium salicylate may inhibit clotting of blood, it is recommended that elective surgery should not be performed on animals within 7 days after the end of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to sodium salicylate or related substances (e.g. aspirin) or excipients should avoid contact with the veterinary medicinal product.
Irritation of the skin, eye, and respiratory tract might occur. During preparation and mixing of the product, direct contact with the skin and eyes, and direct inhalation of the powder

should be avoided. It is recommended to wear gloves, safety glasses, and a dust mask. Particular attention should be taken when opening the bucket.
In case of accidental dermal exposure wash skin immediately with water.
In the event of accidental eye contact, the user is advised to wash the eye with plenty of water for 15 minutes, and seek medical advice if irritation persists.
During administration of medicated drinking water or milk (replacer) to the animals skin contact should be prevented by wearing gloves. Wash accidentally exposed skin immediately with water.

Pregnancy and lactation
Laboratory studies in rats have shown evidence of teratogenic and foetotoxic effects. Salicylic acid crosses the placenta and is excreted with the milk. Half-life in the new-born is longer and thus toxicity symptoms may occur much sooner. Furthermore platelet aggregation is inhibited and bleeding time is increased, a situation which is not favourable during difficult parturition / caesarean section. Finally some studies indicate that delivery is postponed.
The product should not be used during pregnancy and lactation.

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. ketoprofen) for plasma protein binding sites.
Plasma clearance of salicylic acid has been reported to increase in combination with corticosteroids, possibly due to induction of metabolism of salicylic acid.
Concurrent use with other NSAIDs is not recommended, because of increased risk of gastro-intestinal ulcerations.
Do not use in combination with drugs known to have anticoagulant properties.

Overdose (symptoms, emergency procedures, antidotes)
Calves tolerate dosages up to 80 mg/kg for 5 days or 40 mg/kg for 10 days without any adverse effects.
Pigs tolerate dosages up to 175 mg/kg for up to 10 days without any significant adverse effects.
In case of an acute overdose intravenous bicarbonate infusion results in a higher clearance of salicylic acid by alkalisation of the urine and may be beneficial in correcting (secondary metabolic) acidosis.

Incompatibilities
Do not mix with other veterinary medicinal products.

13. 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 products should be disposed of in accordance with local/national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

List of pack sizes:

- Composite can: container consisting of PET/aluminium/adhesive/paper, with a PET/aluminium tear-off membrane and a HDPE lid.
The composite can contains 1 kg of product.
- Securitainer: white polypropylene cylindrical container provided with a low-density polyethylene lid.
The securitainer contains 1 kg of product.
- Bucket: polypropylene bucket provided with a polypropylene lid. The bucket contains 1, 2.5 or 5 kg of product.
Not all pack sizes may be marketed.

Approved 11 March 2022