ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SODIUM SALICYL 80% WSP, powder for oral solution for cattle (calves) and pigs (BE, BG, DE, EE, EL, IT, LT, LV, NL, PT).
SODIUM SALICYL 800 mg/g, powder for oral solution for cattle (calves) and pigs (HU, IE, RO, UK).
SALIMED 800 mg/g, powder for oral solution for cattle (calves) and pigs (PL).
SALIVET 80%, powder for oral solution for cattle (calves) and pigs (FR).
SINTEM 800 mg/g, powder for oral solution for cattle (calves) and pigs (ES).
SODILIN, 800 mg/g, powder for oral solution for cattle (calves) and pigs (DK).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per gram:

Active substance:

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

Excipient:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution.
White or almost-white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves) and pigs.

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

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. 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Calves and pigs:
Meat and offal: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: NSAID

ATCvet-code: QN02BA04

5.1 Pharmacodynamic properties

Sodium salicylate is a non-steroidal 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.

5.2 Pharmacokinetic properties

Orally ingested salicylates are absorbed rapidly by passive diffusion, partly from the stomach but mostly from the upper small intestine.
After absorption, salicylate is distributed throughout most body tissues. Values of volume of distribution (Vd) are higher in the newborns. Half lives are longer in the very young resulting in slower elimination of the substance. This is most prominent in animals up to 7-14 days of age.
The metabolism of salicylate takes mainly place in hepatic endoplasmic reticulum and mitochondria.
Excretion is mainly via the urine and is a pH-dependent process.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

6.2 Major incompatibilities

Do not mix 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 the immediate packaging: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: 4 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

- 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.

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

7. MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands
research@dopharma.com

8. MARKETING AUTHORISATION NUMBER(S)

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

Date of first authorisation:
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Supply on veterinary prescription.

APPENDIX B:

LABELLING AND PACKAGE LEAFLET

I. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

- Composite can
- Bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF THE ACTIVE AND OTHER 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

Calves and pigs:
Meat and offal: zero days.

9. SPECIAL WARNING(S)

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)

17. MANUFACTURER'S BATCH NUMBER

Batch <<partijnummer>>

II. 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 the batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SODIUM SALICYL 80% WSP, 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 animals with known hypersensitivity to sodium salicylate or to 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 serious effects or other effects not mentioned in this leaflet, 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.
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(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

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.

User warnings
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.
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Concurrent administration of potentially nephrotoxic drugs (e.g. aminoglycosides) should be avoided.
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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

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.
- Bucket: polypropylene bucket provided with a polypropylene lid. The bucket contains 1, 2.5 or 5 kg of product.
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