1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium Salicyl 800 mg/g powder for use in drinking water/milk for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:

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

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate

White or almost-white powder.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves) and pigs.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use in animals with severe hypoproteinaemia, liver and kidney affections.
Do not use in case of gastrointestinal ulcerations and chronic gastrointestinal disorders.
Do not use in case of malfunction of the hematopoetic system, coagulopathies, haemorrhagic diathesis.
Do not use 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 the active substance or to the excipient.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product, direct contact with the skin and eyes, and direct inhalation of the powder should be avoided. Personal protective equipment consisting of gloves, safety glasses, and a dust mask should be worn when handling the veterinary medicinal product. Particular attention should be taken when opening the bucket.
In case of accidental dermal exposure wash skin immediately with water.
In case 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves) and pigs:

Undetermined frequency (cannot be estimated from the available data):	Gastrointestinal irritation[1] Melaena[2] Prolonged bleeding[3]

[1] Especially in animals with pre-existing gastrointestinal disease.
[2] Black manure due to blood loss in the gastrointestinal tract is a possible clinical manifestation of gastrointestinal irritation.
[3] Reversible inhibition of normal blood clotting; effects will diminish within approximately 7 days.

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 for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during 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.

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. 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 non-steroidal anti-inflammatory drugs (NSAIDs) is not recommended, because of increased risk of gastro-intestinal ulcerations.
Do not use in combination with drugs known to have anticoagulant properties.

3.9 Administration routes and dosage

In drinking water/milk use.

Calves: 40 mg sodium salicylate per kg of bodyweight once daily,
equivalent to 50 mg veterinary medicinal 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 veterinary medicinal product per kg BW per day),
for 3-5 days.

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

Calves tolerate dosages up to 80 mg/kg for 5 days or 40 mg/kg for 10 days without any adverse events.
Pigs tolerate dosages up to 175 mg/kg for up to 10 days without any significant adverse events.
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.

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

Cattle (calves) and pigs:
Meat and offal: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN02BA04

4.2 Pharmacodynamics

Sodium salicylate is a 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 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water or liquid feed containing biocidal products. Do not mix with any 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 the immediate packaging: 3 months.
Shelf life after dissolution in drinking water according to directions: 24 hours.
Shelf life after dissolution in milk replacer according to directions: 4 hours.

5.3 Special precautions for storage

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

5.4 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 veterinary medicinal product.
- Securitainer: white polypropylene cylindrical container provided with a low-density polyethylene lid.
  The securitainer contains 1 kg of veterinary medicinal product.
- Bucket: polypropylene bucket provided with a polypropylene lid.
  The bucket contains 1, 2.5 or 5 kg of veterinary medicinal 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)

VPA10791/003/001

8. DATE OF FIRST AUTHORISATION

14/10/2011

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

18/06/2026

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).