1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solacyl 1000 mg/g, powder for use in drinking water/milk for cattle and pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Sodium salicylate 1000 mg, equivalent to 862,6 mg of salicylic acid (as sodium salt).

Powder for use in drinking water/milk.
White to off-white flakes.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves) and pigs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not administer in case of severe hypoproteinaemia, liver and kidney disorder.
Do not administer in case of gastrointestinal ulcerations and chronic gastrointestinal disorders.
Do not administer in case of malfunction of the haemopoietic system, coagulopathy, hemorrhagic diathesis.
Do not use sodium salicylates in neonates or calves less than 2 weeks of age.
Do not use in piglets of less than 4 weeks of age.
Do not use in cases of hypersensitivity to the active substance.

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) 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 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.
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 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[a] (tarry or black stool[a+b]), Prolonged bleeding[c]

[a] especially in animals with pre-existing gastrointestinal disease.
[b] due to bleeding in the gastrointestinal tract.
[c] inhibition of normal blood clotting may occur incidentally. This effect is reversible and diminishes 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 combined label-leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation, because 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 increased, which is not favourable during difficult parturition / caesarean section. Finally some studies indicate that parturition 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 ulceration.
Drugs which affect blood clotting should not be used in combination with sodium salicylate.

3.9 Administration routes and dosage

In drinking water/milk use.

Calves: 40 mg sodium salicylate per kg bodyweight once daily, for 1 to 3 consecutive days.
Administration: orally in drinking water or milk (replacer).

Pigs: 35 mg sodium salicylate per kg bodyweight per day, for 3 to 5 consecutive days.
Administration: orally in drinking water.

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:

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

Alternatively the veterinary medicinal product can also be administered with the drinking water as pulse medication. Half of the calculated total daily amount of powder is mixed with 5-10 litres of clean water and stirred until evenly dispersed. This solution is then added, whilst stirring, into an amount of drinking water that will be consumed within approximately 3-4 hours and administered twice daily.
Maximum solubility of the veterinary medicinal product in water is approximately 100 g/litre.
The use of suitably calibrated weighing equipment for the administration of the calculated amount of sodium salicylate is recommended.

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 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.

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:
Pigs: zero days
Calves: zero days
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN02BA04

4.2 Pharmacodynamics

Sodium salicylate is a NSAID and has an anti-inflammatory, analgesic and antipyretic effect. The mode of action is based on inhibition of the enzyme cyclooxygenase, resulting in decreased production of prostaglandin (inflammation mediators).

4.3 Pharmacokinetics

Orally administered sodium salicylate is rapidly absorbed by passive diffusion, partially from the stomach, but mainly from the anterior part of the small intestine. Sodium salicylate distributes very well to the various tissues. Values of volume of distribution (Vd) are higher in the new-borns. 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. Metabolism takes place mainly in the endoplasmic reticulum and the mitochondria of the liver cells.
Elimination occurs mainly via the urine and the pH of the urine can have a major effect on this elimination (see also section 3.10).

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. The veterinary medicinal product can be administered as pulse medication (3-4 hours) twice daily so that if it is to be used in combination with other medications, these can be given separately.

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: 6 months.
Shelf life after dissolution in drinking water according to directions: 24 hours.
Shelf life after dissolution in milk (replacer) according to directions: 6 hours.
After this period, remaining unused solution should be discarded.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bag tightly closed after first opening in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

Sachet/bag with outside to inside layers of white polyethylene terephthalate, polyethylene, aluminium, polyethylene (PET/PE/ALU/PE).

Sachet/bag with outside to inside layers of polyester, polyethylene, aluminium, ionomer (PO/PE/ALU/Ionomer).

Sachet/bag with outside to inside layers of polyethylene terephthalate, aluminium, polyamide, polyethylene (PET/ALU/PA/PE).

Pack sizes: 100 g, 250 g, 500 g, 1 kg, 2,5 kg, and 5 kg.

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

Eurovet Animal Health BV

For BE and LU:
Dechra Regulatory BV

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

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

{DD/MM/YYYY}

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*).