SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solacyl 1000 mg/g, powder for oral solution for cattle and pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains

Active substance:

Sodium salicylate 1000 mg

Excipients:

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for oral solution

White to off-white flakes

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (Calves) and pigs.

4.2 Indications for use, specifying the 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

4.3 Contra-indications

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, haemorrhagic 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 animals with known hypersensitivity to sodium salicylate.

4.4 Special warning for each target species.

None known.

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) 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 inhalation of the powder should be avoided. It is recommended to wear gloves, safety glasses, and a dust mask.
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.

4.6 Adverse reactions (frequency and seriousness)

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

Inhibition of normal blood clotting may occur incidentally. This effect is reversible and diminishes within approximately 7 days.

4.7 Use during pregnancy, lactation or lay

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.

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 ulceration.
Drugs which affect blood clotting should not be used in combination with sodium salicylate.

4.9 Amounts to be administered and administration route

Calves: 40 mg sodium salicylate per kg bodyweight once daily, for 1 to 3 days.

Administration: orally in drinking water or milk(replacer).

Pigs: 35 mg sodium salicylate per kg bodyweight per day, for 3 to 5 days.

Administration: orally in drinking water.

The following formula can be used to calculate the concentration of Solacyl in drinking water or milk:

$$\frac{\text{.....mg [Solacyl] /kg body weight/day} \times \text{mean body weight (kg) of animals to be treated}}{\text{Mean daily water/milk consumption (l) per animal}} = \text{.... mg [Solacyl] per l drinking water / milk}$$

Alternatively Solacyl 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 Solacyl 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.

4.10 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.

4.11 Withdrawal periods

Meat and offal

Pigs: zero days

Calves: zero days

Do not use in cows producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: NSAID. ATC vet code: QN02BA04

5.1. Pharmacodynamic properties

Sodium salicylate is a non-steroid anti-inflammatory drug (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).

5.2 Pharmacokinetic properties

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 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. Metabolism takes place mainly in the endoplasmatic 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 4.10).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

In the absence of compatibility studies, this product must not be mixed with other veterinary medicinal products. Solacyl 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.

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: 6 months
- Shelf-life after reconstitution in drinking water according to directions: 24 hours
- Shelf-life after reconstitution in milk(replacer) according to directions: 6 hours

6.4 Storage precautions

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

6.5 Nature and composition of immediate packaging

Sachets/Bags consisting of the following materials: on the outside a white plastic layer, inside different transparent layers, a sub-layer of aluminium and an inner layer of polyethylene. Pack sizes are 100 g, 250 g, 500 g, 1.0 kg, 2.5 kg and 5.0 kg.

Sachets/Bags consisting of the following materials: on the outside a plastic layer, inside layers of polyethylene and aluminium and an inner layer of ionomer. Pack sizes are 100 g, 250 g, 500 g, 1.0 kg, 2.5 kg and 5.0 kg.

Sachets/Bags consisting of the following materials: on the outside a plastic layer, inside layers of aluminium and polyamide and an inner layer of polyethylene. Pack sizes are 100 g, 250 g, 500 g, 1.0 kg, 2.5 kg and 5.0 kg.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 requirements.

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands.

8. MARKETING AUTHORISATION NUMBER

Vm 16849/4010

9. DATE OF FIRST AUTHORISATION

28 July 2008

10. DATE OF REVISION OF THE TEXT

February 2017

Approved 23 February 2017