PRODUCT INFORMATION

1b-pl-solacyl-day-90 en- clean (renew and var pack) missing changes (3) 6-11-2012

PART IB2
LABEL – QRD TEMPLATE
SOLACYL

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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IMMEDIATE PACKAGE

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LEAFLET

The full text will be printed on the sachet/bag

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

Eurovet Animal Health BV, Handelsweg 25, 5531-AE Bladel, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT AND PHARMACEUTICAL FORM

Solacyl – 1000 mg/g - powder for oral solution for cattle and pigs
Sodium salicylate

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

Composition

Each gram contains
Active Substance:
Sodium salicylate 1000 mg.

4. INDICATION(S)

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

5. 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 haemaopoietic 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this product information, please inform your veterinary surgeon or pharmacist.

7. TARGET SPECIES

Cattle (Calves) and pigs.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

The use of suitably calibrated weighing equipment for the administration of the calculated amount of sodium salicylate is recommended. 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.

10. WITHDRAWAL PERIOD

Meat and offal
Pigs: zero days
Calves: zero days
Do not use in cows producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label after EXP.
Shelf-life after first opening the immediate packaging: 6 months. Keep the bag tightly closed after first opening in order to protect from moisture.
Once opened/broached, use by:
Shelf-life after reconstitution in drinking water according to directions: 24 hours
Shelf-life after reconstitution in milk (replacer) according to directions: 6 hours

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) 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.

Use during 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.

Interactions 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.

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE TEXT WAS LAST APPROVED

October 2012

15. OTHER INFORMATION

Package size: 100 g, 250 g, 500 g, 1.0 kg, 2.5 kg and 5.0 kg.
Not all pack sizes may be marketed.
For animal treatment only
EXP: month/year - Lot {number}