PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

HDPE containers, PET-aluminium-polythene multilayer bags.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salicifarm 1000 mg/g powder for use in drinking water/milk for cattle and pigs (BG, CY, CZ, EL, HR, HU, IT, LT, NL, PL, PT, RO)
Salicifarm powder for use in drinking water/milk for cattle and pigs (FR)

2. COMPOSITION

Each gram contains

Active substance: Salicylic acid 863 mg
(corresponding to sodium salicylate 1000 mg).

White or almost white powder.

3. PACKAGE SIZE

500 g, 1 kg, 5 kg.

4. TARGET SPECIES

Cattle (Calves) and pigs.

5. INDICATIONS FOR USE

Indications for use

Calves: for 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 appropriate (e.g. anti-infective) therapy if necessary;
- to promote recovery of respiration and to reduce coughing in respiratory infections, in combination with concurrent antibiotic therapy.

6. CONTRAINDICATIONS

Contraindications

Do not use in animals suffering from severe hypoproteinaemia, liver and kidney disorder.
Do not use in animals suffering from gastrointestinal ulcerations and chronic gastrointestinal disorders.
Do not use in animals suffering from 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 cases of hypersensitivity to the active substance.

7. SPECIAL WARNINGS

Special warnings

Special precautions for safe use in the target species:
Given that sodium salicylate may inhibit clotting of the 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:
Sodium salicylate may cause hypersensitivity reactions following ingestion, inhalation, or skin contact. People with known hypersensitivity to sodium salicylate or related substances (e.g. aspirin) should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may be harmful following ingestion and dermal contact, and may cause irritation of the skin, eyes and respiratory tract.
Direct contact with the skin and eyes, including hand-to-mouth contact and hand-to-eye contact, and inhalation of the powder should be avoided.
Personal protective equipment consisting of protective clothes, gloves (e.g. rubber or latex), safety glasses, and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) should be worn when handling the veterinary medicinal product. Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use.
In case of accidental dermal exposure wash skin immediately with water. In the event of accidental eye contact, wash the eye with plenty of water for 15 minutes, and seek medical advice if irritation persists.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the package leaflet or label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms that require urgent medical attention.

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, due to its relaxing properties on the uterus, inhibiting platelet aggregation and increased bleeding time, it is contraindicated in the final period of the pregnancy and during difficult births/caesarean section. Finally, some studies indicate that delivery 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 non-steroid anti-inflammatory drugs (NSAIDs) is not recommended, because of increased risk of gastro-intestinal ulceration.
Drugs known to have anticoagulant properties should not be used in combination with sodium salicylate.

Overdose:
Symptoms of overdose can be observed in calves at doses above 80 mg/kg for 5 days or 40 mg/kg for 10 days. 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.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
This veterinary medicinal product may be administered using drinking water containing active chlorine at a maximum concentration of 1 ppm and hydrogen peroxide at a maximum concentration of 35 ppm.
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 (except for chlorine or hydrogen peroxide), feed additives or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events

Cattle (Calves) and pigs:

Undetermined frequency (cannot be estimated on the available data)	Gastrointestinal irritation[1] Prolonged bleeding[2]

[1] especially in animals with pre-existing gastrointestinal disease.
[2] reversible inhibition of normal blood clotting; effect will diminish within approximately 7 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

For administration in drinking water/milk replacer.

Calves: 40 mg sodium salicylate per kg of body weight once daily, for 1 - 3 days.
Pigs: 35 mg sodium salicylate per kg of body weight per day, for 3 - 5 days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of medicated water/milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of sodium salicylate may need to be adjusted accordingly.
The use of suitably calibrated measuring equipment is recommended.

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:

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

The maximum solubility of the veterinary medicinal product tested in milk replacer at 50°C is 10 g /L. Milk replacer should be prepared prior to the addition of the veterinary medicinal product. The solution should be stirred for 5 minutes with a magnetic or mechanical stirrer. Medicated milk replacer should be consumed within 6 hours after preparation.
The maximum solubility of the veterinary medicinal product in water (soft/hard) at 4ºC/20ºC is 250 g /L. The solution should be stirred for 5 minutes with a magnetic or mechanical stirrer. For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated. Medicated drinking water should be freshly prepared every 12 hours. Water uptake should be monitored at frequent intervals during medication. The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated drinking water which is not consumed within 12 hours should be discarded. After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

11. WITHDRAWAL PERIODS

Withdrawal periods

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

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original container in order to protect from light.
The medicated drinking water does not require any special storage conditions.
The medicated milk replacer does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
500 g and 1 kg plastic container.
1 kg and 5 kg multilayer bag.
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
Chemifarma S.p.A.
Via Don Eugenio Servadei, 16 - 47122 Forlì, Italy

Local representative and contact details to report suspected adverse events:

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.
Once opened use by…

Shelf life after dissolution according to directions:

- In drinking water: 12 hours,
- In milk replacer: 6 hours.

21. BATCH NUMBER

Lot {number}