Cylabel®

1000 mg/g powder for use in drinking water/milk

for cattle and pigs

Prescription only
Reg-No: 402392.00.00

Composition
Each gram contains:
Active substances:
Sodium salicylate 1000 mg

White or almost white flakes

Target species
Cattle (Calves), pigs

Indications for use

- 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 a concurrent antibiotic therapy.

Contraindications
Do not use in case of severe hypoproteinaemia, liver and kidney disorder.
Do not use in case of gastrointestinal ulcerations and chronic gastrointestinal disorders.
Do not use in case of malfunction of the haemopoietic system, coagulopathy, haemorrhagic diathesis.
Do not use 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.

Special warnings
Special precautions for safe use in the target species:
Given that sodium salicylate may inhibit blood coagulation, 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:
Irritation of skin, eyes and respiratory tract may occur. Avoid skin and eye contact or any inhalation of the dust of the powder.
Personal protective equipment consisting of protective gloves, (e.g. rubber or latex), safety glasses and an appropriate dust mask (e.g. disposable respirator half-mask conforming to European Standard EN149) should be worn when handling the veterinary medicinal product.
Wash your hands after each use.
In case of accidental dermal exposure wash skin immediately with water. In case of accidental eye contact, wash the eyes with plenty of water for 15 minutes, seek medical advice if irritation persists and show the package leaflet or the label to the physician.

The veterinary medicinal product may cause hypersensitivity. People with known hypersensitivity to sodium salicylate or related drugs (for example, acetylsalicylic acid) should avoid contact with the veterinary medicinal product.
If rash occurs after contact with the veterinary medicinal product, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms that require urgent medical attention.
Do not smoke, eat or drink during handling.

Pregnancy and lactation:
Do not use during pregnancy and lactation.
Laboratory studies in rats have shown evidence of teratogenic and foetotoxic effects. Salicylic acid penetrates the placenta and is excreted in the milk. Since the half-life in newborns is longer, symptoms of toxicity may occur much faster. In addition, the aggregation of platelets is slowed down and the bleeding time is prolonged, which is an unfavourable situation during dystocia or caesarean section. Some studies also indicate that delivery is delayed.

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 coagulation should not be used in combination with sodium salicylate.

Overdose:
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.

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.

Adverse events
Cattle (Calves), pigs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Gastrointestinal irritation [1] Black stool [2] Coagulopathy [3]

[1] especially in animals with pre-existing gastrointestinal disease
[2] due to bleeding in the gastrointestinal tract
[3] Inhibition of normal blood coagulation. Reversible, diminishes within approximately 7 days

If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian.

Dosage for each species, routes and method of administration

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

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

In drinking water/milk use.

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:

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

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 600 g/litre.
The use of suitably calibrated measuring equipment is recommended.

Advice on correct administration

See section "Dosage for each species, routes and method of administration"

Withdrawal periods

Meat and offal	Pigs:	zero days
	Calves:	zero days

Special storage precautions

Keep out of the sight and reach of children.
Store in the original package.
Keep the package tightly closed in order to protect from light.
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.

Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after reconstitution in drinking water according to directions: 24 hours
Shelf-life after reconstitution in milk/ milk replacer according to directions: 6 hours

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.

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

Pack sizes
Carton box with 1 kg or bag with 5 kg
Not all pack sizes may be marketed.

Date on which the package leaflet was last revised
06/2025
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).