SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cylabel 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

3. PHARMACEUTICAL FORM

Powder for use in drinking water/milk.
White or almost white flakes

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (Calves), 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 a concurrent antibiotic therapy.

4.3 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, 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 warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
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.
When applying the product, the user should wear 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).
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 product may cause hypersensitivity. People with known hypersensitivity to sodium salicylate or related drugs (for example, acetylsalicylic acid) should avoid contact with the product.
If rash occurs after contact with the 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.

4.6 Adverse reactions (frequency and seriousness)

Gastrointestinal irritation especially in animals with pre-existing gastrointestinal disease have been reported very rarely in spontaneous reports. Such irritation may be clinically manifested by production of black faeces due to bleeding in the gastrointestinal tract.
Inhibition of normal blood coagulation may occur in very rare cases. This effect is reversible and diminishes within approximately 7 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.
Laboratory studies in rats data revealed 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.

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 coagulation 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 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.

Route of administration: oral, via milk/ milk replacer or the drinking water.
The following formula can be used to calculate the concentration of the product in drinking water or milk/milk replacer:

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

Alternatively the 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 completely dissolved. 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 product in water is approximately 600 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), 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.

4.11 Withdrawal period(s)

Meat and offal

Pigs: zero days

Calves: zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nervous System, Analgesics, other Analgesics and Antipyretics, Salicylic acid and derivatives

ATCvet code: QN02BA04

5.1 Pharmacodynamic properties

Sodium salicylate is a non-steroidal anti-inflammatory drug (NSAID) and has an anti-inflammatory, analgesic and antipyretic effect. It works by inhibiting the enzyme cyclo-oxygenase which results in the decrease of the production of prostaglandin (inflammation mediator).

5.2 Pharmacokinetic particulars

Orally administered salicylates are rapidly absorbed by passive diffusion, in part from the stomach but largely from the anterior part of the small intestine. Sodium salicylate is distributed well across the different tissues. Metabolism occurs primarily in the endoplasmic reticulum and the mitochondria of the liver cells. Excretion takes place mainly through urine and urinary pH plays a major role in the elimination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
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

6.4. Special precautions for storage

Store in the original package.
Keep the package tightly closed in order to protect from light.

6.5 Nature and composition of immediate packaging

Carton box with 1 kg powder: fold-up carton with inner layer (paper/PE/Alu/PE)
Bag with 5 kg powder: kard-o-seal-bag (PE/paper/PE/Alu/PE).
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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

11. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

B. COMBINED LABELLING

Full information of package leaflet and label are provided
(1 kg box, 5 kg bag)

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

{1 kg box, 5 kg bag }

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

Marketing authorisation holder and manufacturer responsible for batch release:
bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

2. Name of the veterinary medicinal product

Cylabel 1000 mg/g powder for use in drinking water/milk for cattle and pigs
Sodium salicylate

3. Statement of the active substance (s) and other ingredients

Each gram contains:

Active substance:
Sodium salicylate 1000 mg

White or almost white flakes

4. Pharmaceutical form

Powder for use in drinking water/milk

5. Package size

1 kg
5 kg

6. 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 a concurrent antibiotic therapy.

7. 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, 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.

8. Adverse reactions

Gastrointestinal irritation especially in animals with pre-existing gastrointestinal disease have been reported very rarely in spontaneous reports. Such irritation may be clinically manifested by production of black faeces due to bleeding in the gastrointestinal tract.
Inhibition of normal blood coagulation may occur in very rare cases. This effect is reversible and diminishes within approximately 7 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Cattle (Calves), pigs

10. Dosage for each species, route(s) 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.

Route of administration: oral, via milk/ milk replacer or the drinking water.

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

.....mg product / kg body weight/day	x	mean body weight (kg) of animals to be treated	= .... mg product per l

Mean daily water/milk consumption (l) per animal	drinking water / milk

Alternatively the 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 product in water is approximately 600 g/litre.
The use of suitably calibrated weighing equipment for the administration of the calculated amount of sodium salicylate is recommended.

11. Advice on correct administration

Not applicable.

12. Withdrawal period(s)

Withdrawal period(s):

Meat and offal
Pigs: zero days
Calves: zero days

13. Special storage precautions

Store in the original package.
Keep the package tightly closed in order to protect from light.

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

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.

14. Special warning(s)

Special precautions for use in animals:
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.
When applying the product, the user should wear 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).

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 product may cause hypersensitivity. People with known hypersensitivity to sodium salicylate or related drugs (for example, acetylsalicylic acid) should avoid contact with the product.
If rash occurs after contact with the 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:
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Interaction with other medicinal products and other forms of interaction:
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Overdose (symptoms, emergency procedures, antidotes):
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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.

Incompatibilities:
In the absence of compatibility studies, this product must not be mixed with other veterinary edicinal products. The 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.

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

17. Other information

Pack sizes: 1 kg or 5 kg

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

[To be completed nationally]

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

<EXP {month/year}>

Once opened use by…

21. Marketing authorisation number(s)

22. Manufacturer's batch number

<Batch>