

[Version 9.1,11/2024]

ANNEX I

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 substances:

Sodium salicylate 1000 mg

White or almost white flakes

3. CLINICAL INFORMATION

3.1 Target species

Cattle (Calves), pigs

3.2 Indications for use for each 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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder **<or its local representative>** or the national competent authority via the national reporting system. See the **<package leaflet>** **<immediate packaging>** for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy and lactation.

Laboratory studies in 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.

3.8 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.

3.9 Administration routes and dosage

In drinking water/milk use.

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.

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:

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

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 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 veterinary medicinal product in water is approximately 600 g/litre.

The use of suitably calibrated measuring equipment is recommended.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 alkalinisation of the urine and may be beneficial in correcting (secondary metabolic) acidosis.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal

Pigs: zero days

Calves: zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QN02BA04

4.2 Pharmacodynamics

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).

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

5.2 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

5.3 Special precautions for storage

Store in the original package.

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

bela-pharm GmbH & Co.KG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1kg box, 5kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active substances:

Sodium salicylate

1000 mg

3. PACKAGE SIZE

1kg, 5kg

4. TARGET SPECIES

Cattle (Calves), pigs

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

In drinking water/milk use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal

Pigs: zero days

Calves: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months, by...

Once reconstituted in drinking water use within 24 hours.

Once reconstituted in milk/milk replacer use within 6 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package.

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

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| 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE” |
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Read the package leaflet before use.

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| 11. THE WORDS “FOR ANIMAL TREATMENT ONLY” |
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For animal treatment only.

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| 12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN” |
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Keep out of the sight and reach of children.

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|---|
| 13. NAME OF THE MARKETING AUTHORISATION HOLDER |
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belapharm GmbH & Co.KG

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| 14. MARKETING AUTHORISATION NUMBERS |
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|-------------------------|
| 15. BATCH NUMBER |
|-------------------------|

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

Active substances:

Sodium salicylate 1000 mg

White or almost white flakes

3. Target species

Cattle (Calves), pigs

4. 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.

5. 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.

6. 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 alkalinisation 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.

7. 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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. 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.

9. Advice on correct administration

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

10. Withdrawal periods

Meat and offal

Pigs: zero days

Calves: zero days

11. 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

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes: carton box with 1 kg or bag with 5 kg

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany
Tel.: +49 4441 873 555

Local representatives and contact details to report suspected adverse events:

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

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 OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each gram contains:

Active substances:

Sodium salicylate 1000 mg

White or almost white flakes

3. PACKAGE SIZE

1 kg, 5 kg

4. TARGET SPECIES

Cattle (Calves), pigs

5. INDICATIONS FOR USE

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.

6. CONTRAINDICATIONS

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.

7. SPECIAL WARNINGS

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 alkalinisation 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.

| |
|--------------------------|
| 8. ADVERSE EVENTS |
|--------------------------|

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

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: {national system details}

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

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:

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

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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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

11. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal

Pigs: zero days
Calves: zero days

12. SPECIAL STORAGE PRECAUTIONS

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.

13. SPECIAL PRECAUTIONS FOR THE 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

Carton box with 1 kg or bag with 5 kg

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

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:

Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany
Tel.: +49 4441 873 555

Local representatives and contact details to report suspected adverse events:

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

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 3 months, by...

Once reconstituted in drinking water use within 24 hours.

Once reconstituted in milk/milk replacer use within 6 hours.

21. BATCH NUMBER

Lot {number}