[Version 9.1, 11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bacivet S, 4200 IU/g, powder for use in drinking water, rabbits [BE, CZ, DE, EL, ES, FR, HU, IT, NL]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram (g) contains:

Active substance:
Bacitracin zinc 4200 IU

Excipients:

Qualitative composition of excipients and other constituent
Citric acid anhydrous
Sodium citrate
Colloidal silica anhydrous
Lactose monohydrate

White to light yellow free flowing powder.

3. CLINICAL INFORMATION

3.1 Target species

Rabbits for fattening.

3.2 Indications for use for each target species

Rabbits for fattening:
At the flock level: reduction of clinical signs and mortality due to epizootic enterocolitis associated with infections caused by *Clostridium perfringens*, sensitive to bacitracin.

3.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of excipients.

3.4 Special warnings

Before installing a treatment, the management and sanitary conditions at the farm should be evaluated against the risk of an outbreak of the disease. The treatment should be installed if there is a known history of epizootic enterocolitis at the farm and as soon as the first case of mortality due to enterocolitis has been confirmed.

3.5 Special precautions for use

Special precautions for safe use in the target species

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to

bacitracin zinc and may decrease the effectiveness of treatment with other classes of antimicrobials, due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Bacitracin can occasionally cause hypersensitivity reactions after inhalation or skin contact. Do not manipulate this veterinary medicinal product in case of known allergy to bacitracin or when the person has received the recommendation to avoid working with this preparation.

Avoid inhalation of dust when incorporating the veterinary medicinal product, and to avoid all contact with it, follow the recommendations for use: it is recommended to wear a mask, security glasses, protection gloves and protection clothing. After preparation and administration of the solution, wash hands. In case of skin contact, rinse excessively with clear water.
In case of observations of symptoms such as skin eruptions after exposure to the veterinary medicinal product or a persistent eye irritation in case of projection, consult a medical doctor and show him this precaution text. Swelling of the face, lips or eyebrows and breathing difficulties are serious signs and need urgent medical care.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Rabbits:
None known.

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 for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in laboratory animals (rats) have not shown evidence of teratogenic or embryotoxic effects of zinc bacitracin at a therapeutic dose. The safety of the veterinary medicinal product in pregnant or lactating breeding rabbits has not been demonstrated. The use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

In drinking water use.

420 IU bacitracin / kg bodyweight / day (corresponding to 100 mg of veterinary medicinal product / kg bodyweight or 1 bag / 1000 kg bodyweight), for 14 days.
Start treatment once the first case of mortality due to enterocolitis has been confirmed. After evaluation of the therapeutic response, the duration of treatment can be prolonged by 7 days if necessary.
In order to facilitate a correct dosing, it is advised to dilute the veterinary medicinal product first in a stock solution. Since this concentrated stock solution might not be stable it should immediately be further diluted to the final concentration. To ensure a correct dosage, body weight should be determined as accurately as possible.

For example: in order to obtain a final dilution suitable for animals consuming 150 ml of water per kg

bodyweight daily, the following schedule can be used: a concentrated stock solution with 13,5 g of veterinary medicinal product per liter is prepared, and this is then incorporated *a ratio* of 5 % in the final drinking water in order to obtain a concentration of 670 mg of veterinary medicinal product per liter water. The preparation then contains approximately 100 mg of bacitracin zinc for 150 ml. This solution of drinking water is given *ad libitum* to the animals. The intake of medicated feed and water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of bacitracin may need to be adjusted accordingly. For example:

Water consumption (% of body weight)	Quantity of veterinary medicinal product to incorporate per liter of drinking water
10%	1000 mg
15%	670 mg
20%	500 mg

A new solution should be prepared daily during the treatment period.

3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes)

No undesirable effects have been observed after administration of the veterinary medicinal product at 5 times the recommended dose level.

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 period(s)

Meat and offal: 2 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QA07AA93

4.2 Pharmacodynamics

Bacitracin is a polypeptide antibiotic and is a mixture of several closely related polypeptides. It inhibits cell wall biosynthesis by inhibiting lipid pyrophosphatase which is involved in transmembrane transport of peptidoglycan precursors. The zinc salt confers stability to the active substance during storage.
Bacitracin has bactericidal properties. Its spectrum included primarily Gram-positive cocci and bacilli, particularly some species of Clostridiae.
There are no Clinical and Laboratory Standards Institute (CLSI) interpretive criteria available, but MIC values of 2 μg/ml or less have been proposed as very susceptible and MIC values above 16 μg/ml as resistant. Resistance is of the chromosomal type and is therefore acquired slowly and not transferable. There are no known cross-resistance and co-resistance. In rabbits, resistance of *Clostridium perfringens* against bacitracin is considered to be rare.

4.3 Pharmacokinetics

After oral administration of bacitracin *ad libitum* in the drinking water at a dose level of 420 IU/kg/day,

the concentrations in the caecal content were above 2 µg/ml during 24 hours. Bacitracin is hardly absorbed after oral administration in rabbits.

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.

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: use immediately.
Shelf life after dilution or reconstitution according to directions: 24 hours.

5.3. Special precautions for storage

Do not store above 30 °C.

5.4. Nature and composition of immediate packaging

Low density polyethylene / aluminium / polyester bag.
Box containing 10 bags of 100 g.

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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

To be completed nationally.

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

To be completed nationally.

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 10 bags of 100 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bacivet S, 4200 IU/g, powder for use in drinking water, rabbits.

2. STATEMENT OF ACTIVE SUBSTANCES

Bacitracin zinc 4200 IU/g

3. PACKAGE SIZE

Box containing 10 bags of 100 g.

4. TARGET SPECIES

Rabbits for fattening.

6. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Powder for use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 2 days

8. EXPIRY DATE

Once the sachet is opened: use immediately.
Once dissolved: 24 hours.

EXP (month/year)

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

HUVEPHARMA NV

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS

100 g low density polyethylene / aluminium / polyester bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bacivet S, 4200 IU/g, powder for use in drinking water, rabbits.

2. STATEMENT OF ACTIVE SUBSTANCES

Bacitracin zinc 4200 IU/g

3. TARGET SPECIES

Rabbits for fattening.

4. ROUTES OF ADMINISTRATION

Powder for use in drinking water.

Read the package leaflet before use

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 2 days

6. EXPIRY DATE

EXP (mm/yyyy)

Once opened: use immediately.
Once dissolved: 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Bacivet S, 4200 IU/g, powder for use in drinking water, rabbits

1. Name of the veterinary medicinal product

Bacivet S, 4200 IU/g, powder for use in drinking water, rabbits.

2. Composition

Each gram contains:

Active substance:
Bacitracin zinc 4200 IU

White to light yellow free flowing powder.

3. Target species

Rabbits for fattening.

4. Indications for use

Rabbits for fattening:
At the flock level: reduction of clinical signs and mortality due to epizootic enterocolitis associated with infections caused by *Clostridium perfringens*, sensitive to bacitracin.

5. Contraindications

Do not use in case of hypersensitivity to the active substance or to any of excipients.

6. Special warning

Special warnings

Before installing a treatment, the management and sanitary conditions at the farm should be evaluated against the risk of an outbreak of the disease. The treatment should be installed if there is a known history of epizootic enterocolitis at the farm and as soon as the first case of mortality due to enterocolitis has been confirmed.

Special precautions for safe use in the target species

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to bacitracin zinc and may decrease the effectiveness of treatment with other classes of antimicrobials, due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Bacitracin can occasionally cause hypersensitivity reactions after inhalation or skin contact. Do not manipulate this veterinary medicinal product in case of known allergy to bacitracin or when the person has received the recommendation to avoid working with this preparation.

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In case of observations of symptoms such as skin eruptions after exposure to the product or a persistent eye irritation in case of projection, consult a medical doctor and show him this precaution text. Swelling of the face, lips or eyebrows and breathing difficulties are serious signs and need urgent medical care.

Pregnancy and lactation:

Laboratory studies in laboratory animals (rats) have not shown evidence of teratogenic or embryotoxic effects of zinc bacitracin at a therapeutic dose. The safety of the veterinary medicinal product in pregnant or lactating breeding rabbits has not been demonstrated. The use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

None known.

Overdose

No undesirable effects have been observed after administration of the product at 5 times the recommended dose level.

Incompatibilities

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

7. Adverse events

None known.

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, route(s) and method of administration

In drinking water use:

420 IU bacitracin / kg bodyweight / day (corresponding to 100 mg of veterinary medicinal product / kg bodyweight or 1 bag / 1000 kg bodyweight), for 14 days.
Start treatment once the first case of mortality due to enterocolitis has been confirmed. After evaluation of the therapeutic response, the duration of treatment can be prolonged by 7 days if necessary.

9. Advice on correct administration

In order to facilitate a correct dosing, it is advised to dilute the veterinary medicinal product first in a stock solution. Since this concentrated stock solution might not be stable it should immediately be further diluted to the final concentration. To ensure a correct dosage, body weight should be determined as accurately as possible.

For example: in order to obtain a final dilution suitable for animals consuming 150 ml of water per kg bodyweight daily, the following schedule can be used: a concentrated stock solution with 13,5 g of veterinary medicinal product per liter is prepared, and this is then incorporated *a ratio* of 5 % in the final drinking water in order to obtain a concentration of 670 mg of veterinary medicinal product per liter water. The preparation then contains approximately 100 mg of bacitracin zinc for 150 ml. This solution of drinking water is given *ad libitum* to the animals. The intake of medicated feed and water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of bacitracin may need to be adjusted accordingly. For example:

Water consumption (% of body weight)	Quantity of veterinary medicinal product to incorporate per liter of drinking water
10%	1000 mg
15%	670 mg
20%	500 mg

A new solution should be prepared daily during the treatment period.

10. Withdrawal periods

Meat and offal: 2 days

11. Special storage precautions

Keep out of the sight and reach of children.

Product as packed for sale: do not store above 30°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the bag after “EXP”. The expiry date refers to the last day of that month.

Shelf life after first opening of the immediate packaging: use immediately.
Shelf life after dilution or reconstitution according to directions: 24 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 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

Box containing 10 bags of 100 g.

14. Date on which the package leaflet was revised

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

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse events:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

Manufacturer responsible for batch release:
CEVA SANTE ANIMALE
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNÉ
France

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.

15. OTHER INFORMATION