ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procipen 300 mg/ml suspension for injection for cattle sheep and pigs
Benzylpenicillin procaine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active Substance: Benzylpenicillin procaine 300 mg
(corresponding to 175.8 mg of benzylpenicillin)

Excipient: Methyl Parahydroxybenzoate E218 2.0 mg

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

100 ml
250 ml
12x100 ml
12x250 ml
48x100 ml
48x250 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

For the treatment of acute systemic infections caused by bacteria susceptible to benzylpenicillin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle

Meat and offal: 10 days
Milk: 108 hours (4.5 days)
Pigs
Meat and offal: 7 days
Sheep
Meat and offal: 4 days
Not authorised for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for user warnings.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {MM/YYYY}
Shelf life after first broaching the vial: 28 days. Once opened, use by: …./…./….

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Not required on the immediate label

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

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

Not required on the immediate label

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/4041

17. MANUFACTURER'S BATCH NUMBER

Batch no.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Procipen 300 mg/ml suspension for injection for cattle sheep and pigs

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:
Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procipen 300 mg/ml suspension for injection for cattle sheep and pigs
Benzylpenicillin procaine

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of off-white liquid suspension contains:
Active substance
Benzylpenicillin procaine 300 mg
(corresponding to 175.8 mg benzylpenicillin)
Excipients
Methyl Parahydroxybenzoate E218 2.0 mg

4. INDICATION(S)

For the treatment of acute systemic infections caused by bacteria susceptible to benzylpenicillin.

5. CONTRAINDICATIONS

Do not inject intravenously.
Do not use in known cases of hypersensitivity to penicillin, cephalosporins, procaine or to any of the excipients.
Do not use in case of severe renal dysfunction with anuria and oliguria.
Do not use in very small herbivores such as guinea pigs, gerbils and hamsters.
Do not use in the presence of β-lactamase producing pathogens.

6. ADVERSE REACTIONS

In suckling and fattening pigs, administration of the product may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination uncommonly.
Anaphylactic reactions may occur in rare cases in cattle, due to the povidone content.
Allergies to penicillin have been observed but these are very rare. Reactions may occasionally be serious and include anaphylactic shock.

In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.
In case of side effects, the animal should be treated symptomatically.

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 package leaflet 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}

7. TARGET SPECIES

Cattle, sheep and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular use only.
Dosage: 12 mg procaine benzylpenicillin (corresponding to 7 mg benzylpenicillin) per kg bodyweight (equivalent to 2 ml of the product per 50 kg bw) per day for 3 consecutive days. Do not discontinue treatment before 3 days.
If no significant clinical improvement is noted within 3 days, the initial diagnosis should be reassessed and the treatment should be changed, if necessary.
The maximum volumes to be injected at any one site are 20 ml (Cattle), 3 ml (Pigs) and 2 ml (Sheep).
The vials can only be broached a maximum of 30 times.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Before use, shake the vial gently for a minimum of 10 seconds until all sediment is readily dispersed.

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD(S)

Cattle
Meat and offal: 10 days
Milk: 108 hours (4.5 days)
Pigs
Meat and offal: 7 days
Sheep
Meat and offal: 4 days

Not authorised for use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Shelf life after first opening the container: 28 days
Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Complete cross-resistance has been shown between benzylpenicillin procaine and other penicillins.

Special precautions for use in animals:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and cephalosporins due to the potential for cross-resistance.
The feeding of waste milk containing residues of antibiotics to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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

Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
This product also contains a paraben preservative which may cause a contact hypersensitivity reaction in previously sensitised individuals.
Do not handle this product if you know that you are sensitized, or if you have been advised not to work with such preparations. People developing a reaction after contact with the product should avoid handling the product and other penicillin and cephalosporin containing products in the future.
It is recommended to wear gloves when handling and administering the product.
Handle this product with care to avoid exposure.

In case of accidental contact with eyes, rinse immediately with copious amounts of water. Accidental spillage on the skin should be washed immediately with soap and water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips, eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:

There is no evidence that this product presents any particular hazard to the dam or foetus. However, in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.
Use during pregnancy and lactation only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

The effect of aminoglycosides can be enhanced by penicillins.
The bactericidal efficacy of penicillin is counteracted by bacteriostatic medicinal products.
The excretion of benzylpenicillin is prolonged by acetylsalicylic acid. Cholinesterase inhibitors delay the degradation of procaine.
Benzylpenicillin is bactericidal. Avoid concurrent use of bactericidal and bacteriostatic antibiotics as they can antagonise the bactericidal effect of penicillins.

Overdose (symptoms, emergency procedures, antidotes):

Tolerance studies have been conducted at twice the recommended dosage rate in all three target species without any ill-effects being observed.
In the case of overdose, central nervous symptoms and/or convulsions may occur.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 1 x 100 ml, 12 x 100 ml, 48 x 100 ml, 1 x 250 ml, 12 x 250 ml, 48 x 250 ml.
Not all pack sizes may be marketed.

Approved 18 June 2021