ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with one 100 ml vial
Box with one 250 ml bottle
Box with 10 boxes containing 1 vial of 100 ml
Box with 30 boxes containing 1 vial of 100 ml
Box with 12 boxes containing 1 bottle of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs

Procaine benzylpenicillin monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Benzylpenicillin procaine monohydrate 300 mg
(corresponding to 170.40 mg benzylpenicillin)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml
10x100 ml
30x100 ml
12x250 ml

5. TARGET SPECIES

Cattle, sheep and pigs (> 25 kg)

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use . Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period:
Pigs:
Meat and offal: 6 days

Cattle:
Meat and offal: 6 days
Milk: 96 hours (4 days)

Sheep:
Meat and offal: 4 days
Milk: 156 hours (6.5 days)

9. SPECIAL WARNINGS, IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Once opened use by: <Only for individual box>
Shelf life after first opening the immediate packaging: 28 days at 2ºC-8ºC.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator
Keep the vial/bottle in the outer carton in order to protect from light.

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

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”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.U
Avda. Párroco Pablo Díez 49-57
24010 León
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31592/3000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml vial label
250 ml bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procactive 300 mg/mlsuspension for injection for cattle, sheep and pigs.

Procaine benzylpenicillin monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Benzylpenicillin procaine monohydrate……..300 mg
(corresponding to 170.40 mg benzylpenicillin)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, sheep and pigs (> 25 kg)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use. Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Pigs:
Meat and offal: 6 days

Cattle:
Meat and offal: 6 days
Milk: 96 hours (4 days)

Sheep:
Meat and offal: 4 days
Milk: 156 hours (6.5 days)

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use by:
Shelf life after first opening the immediate packaging: 28 days at 2ºC- 8ºC.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator
Keep the vial/bottle in the outer carton in order to protect from light.

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.U
Avda. Párroco Pablo Díez 49-57
24010 León
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 31592/3000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Procactive 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:

Laboratorios SYVA S.A.U
Avda. Párroco Pablo Díez 49-57
24010 León
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs.

Procaine benzylpenicillin monohydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:
Benzylpenicillin procaine monohydrate……..300 mg/ml
(corresponding to 170.40 mg benzylpenicillin)
Excipients:
Sodium methyl parahydroxybenzoate (E219)……...1.25 mg/ml

White suspension

4. INDICATIONS

For the treatment of systemic infections in cattle, sheep and pigs (weighing more than 25 kg) caused by or associated with bacteria susceptible to benzylpenicillin.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

In suckling and fattening pigs, pyrexia, vomiting, shivering, listlessness and incoordination have been reported rarely, which may be caused by the release of procaine.
In pregnant sows and gilts, a vulvar discharge which could be associated with abortion has been reported rarely.
In cattle, anaphylactic reactions have been reported rarely, which may be caused by the content of povidone.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following administration of the product. Allergic reactions to these substances may occasionally be serious and include anaphylactic shock.

In case of side effects, the animal has to 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 reactions)
- 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 (weighing more than 25 kg).

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

For intramuscular use.
The recommended dosage rate is 10 mg/kg bodyweight procaine benzylpenicillin (corresponding to 5.66 mg benzylpenicillin/kg bodyweight) equivalent to 1 ml per 30 kg bodyweight daily for 3-5 days.
Do not inject more than 2.5 ml per injection site in pigs.
Do not inject more than 12 ml per injection site in cattle.
Do not inject more than 2 ml per injection site in sheep.
If no clinical response is seen within 3 days, redetermine the diagnosis and change the treatment if necessary.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial to ensure re-suspension before administering the product.

Do not mix with another substance in the same syringe. Disinfect the cap before extracting each dose. Use a sterile dry syringe and needle. The cap may be safely punctured up to 50 times.

10. WITHDRAWAL PERIOD(S)

Pigs:
Meat and offal: 6 days

Cattle:
Meat and offal: 6 days
Milk: 96 hours (4 days)

Sheep:
Meat and offal: 4 days
Milk: 156 hours (6.5 days)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2ºC-8ºC).
Keep the vial/bottle in the outer carton 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: 28 days at 2ºC-8ºC.

12. SPECIAL WARNINGS

Special warnings for each target species:

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

Special precautions for use in animals:

The product is not to be used in pigs weighing less than 25 kg bodyweight.
Administer by deep injection only.
The 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 this 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 hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity 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.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

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.
In case of accidental eye contact, rinse thoroughly with water.
In case of accidental skin contact wash exposed skin thoroughly 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.

Pregnancy and lactation:

There is no evidence that this product presents any particular hazard to the dam or foetus.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. However, in pregnant sows and gilts, a vulvar discharge which could be associated with abortion has been reported.

Use during pregnancy and lactation only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

The bactericidal efficacy of penicillin is counteracted by bacteriostatic medicinal products.
The effect of aminoglycosides can be enhanced by penicillins.
The excretion of benzylpenicillin is prolonged by acetylsalicylic acid.
Cholinesterase inhibitors delay the degradation of procaine.

Overdose (symptoms, emergency procedures, antidotes):

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

DD/MM/YYYY

15. OTHER INFORMATION

In vitro tests have shown the following organisms to be sensitive*: Erysipelothrix rhusiopathiae, Listeria* spp*., Mannheimia haemolytica, Pasteurella multocida, Staphylococcus* spp. (non-penicillinase producing), *Streptococcus* spp. and *Trueperella pyogenes.*

Pack sizes: Carton box with 1 vial of 100 ml
Carton box with 1 bottle of 250 ml
Carton box with 10 boxes containing 1 vial of 100 ml
Carton box with 30 boxes containing 1 vial of 100 ml
Carton box with 12 boxes containing 1 bottle of 250 ml

Not all pack sizes may be marketed.

Marketing Authorisation Number:

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

Approved 09 June 2022