

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

100 ml
250 ml
10 x 100 ml
30 x 100 ml
12 x 250 ml

4. TARGET SPECIES

Cattle, sheep and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs:

Meat and offal: 6 days for treatment duration 3-5 days
8 days for treatment duration 6-7 days

Cattle:

Meat and offal: 6 days for treatment duration 3-5 days
8 days for treatment duration 6-7 days

Milk: 96 hours (4 days)

Sheep:

Meat and offal: 4 days for treatment duration 3-5 days
6 days for treatment duration 6-7 days

Milk: 156 hours (6.5 days)

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by:

Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.

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

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

Read 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

Laboratorios Syva, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 31592/3000

15. BATCH NUMBER

Lot {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/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Benzylpenicillin procaine monohydrate.....300 mg
(corresponding to 170.40 mg benzylpenicillin)

3. TARGET SPECIES

Cattle, sheep and pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs:

Meat and offal: 6 days for treatment duration 3-5 days
8 days for treatment duration 6-7 days

Cattle:

Meat and offal: 6 days for treatment duration 3-5 days
8 days for treatment duration 6-7 days
Milk: 96 hours (4 days)

Sheep:

Meat and offal: 4 days for treatment duration 3-5 days
6 days for treatment duration 6-7 days
Milk: 156 hours (6.5 days)

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by:
Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Syva S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Benzylpenicillin procaine monohydrate.....300 mg
(corresponding to 170.40 mg benzylpenicillin)

Excipients:

Sodium methyl parahydroxybenzoate (E219).....1.25 mg

White suspension.

3. Target species

Cattle, sheep and pigs.

4. Indications for use

For the treatment of systemic infections in cattle, sheep and pigs caused by or associated with bacteria susceptible to benzylpenicillin.

5. Contraindications

Do not inject intravenously.

Do not use in cases of hypersensitivity to the active substance, 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. Special warnings

Special warnings:

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

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g. blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the veterinary medicinal product for treatment of meningitis or CNS infections due to e.g. *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly, hence this veterinary medicinal product may have little effect in treating intracellular pathogens e.g. *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:

- *Glaesserella parasuis*, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs;
- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica* (only in some member states), as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

Special precautions for safe use in target species:

Administer by deep injection only.

The use of the veterinary medicinal 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 veterinary medicinal product is used.

Use of the veterinary medicinal 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 colostrum 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 veterinary medicinal product also contains a paraben preservative which may cause a contact hypersensitivity reaction in previously sensitised individuals.

1. People with known hypersensitivity to this veterinary medicinal product, or if you have been advised not to work with such preparations, should avoid contact with the veterinary medicinal product.
2. Handle this veterinary medicinal 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 package leaflet or the label to the physician. 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 veterinary medicinal product should avoid handling the veterinary medicinal product and other penicillin and cephalosporin containing products in the future.

Personal protective equipment consisting of gloves should be worn when handling and administering the veterinary medicinal 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:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

There is no evidence that this veterinary medicinal product presents any particular hazard to the dam or foetus. However, in pregnant sows and gilts, a vulvar discharge which could be associated with abortion has been reported.

Use only according 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:

In the case of overdose, central nervous symptoms and/or convulsions may occur.

Special restrictions for use and special conditions for use:

Major incompatibilities:

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

7. Adverse events

Cattle:

Rare (1 to 10 animals / 10 000 animals treated):

Anaphylactic-type reaction ¹ , Hypersensitivity reaction ² , Anaphylactic shock ² .
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1. May be caused by the content of povidone.
2. May be caused by penicillins and cephalosporins following administration. May occasionally be serious.

Sheep:

Rare (1 to 10 animals / 10 000 animals treated):

Hypersensitivity reaction ¹ , Anaphylactic shock ¹ .
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1. May be caused by penicillins and cephalosporins following administration. May occasionally be serious.

Pigs:

Rare (1 to 10 animals / 10 000 animals treated):

Pyrexia ¹ , Listless ¹ , Systemic disorder ² ; Vomiting ¹ ; Shivering ¹ , Incoordination ¹ ; Vaginal discharge ³ ; Hypersensitivity reaction ⁴ , Anaphylactic shock ⁴ .
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1. In suckling and fattening pigs. May be caused by the release of procaine.
2. Toxic effects have been observed in young piglets. Transient but can be potentially lethal, especially at higher doses.
3. In pregnant sows and gilts. Could be associated with abortion.
4. May be caused by penicillins and cephalosporins following administration. May occasionally be serious.

In case of side effects, the animal has to be treated symptomatically.

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 and method of administration

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. The treatment duration is 3 to 7 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.

The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitability calibrated measuring equipment is recommended.

9. Advice on correct administration

Shake the vial to ensure re-suspension before administering the veterinary medicinal 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 periods

Pigs:

Meat and offal: 6 days for treatment duration 3-5 days
8 days for treatment duration 6-7 days

Cattle:

Meat and offal: 6 days for treatment duration 3-5 days
8 days for treatment duration 6-7 days

Milk: 96 hours (4 days)

Sheep:

Meat and offal: 4 days for treatment duration 3-5 days
6 days for treatment duration 6-7 days

Milk: 156 hours (6.5 days)

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C-8°C).

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.

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

Vm 31592/3000

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Laboratorios SYVA S.A.
Calle Marqués de la Ensenada, 16
28004 Madrid
Spain

Manufacturer responsible for batch release:

Laboratorios Syva S.A.
Avenida del Párroco Pablo Díez, 49-57
San Andrés del Rabanedo
24010 León
Spain

Local representative 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.

17. Other information

Gavin Hall
Approved: 06 January 2026