

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}**

**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 mg benzylpenicillin)

**3. PACKAGE SIZE**

100 ml

250 ml

10x100 ml

30x100 ml

12x250 ml

**4. TARGET SPECIES**

Cattle and pigs (> 25 kg)

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

For 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)

**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**

31592/5001

## **15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {NATURE/TYPE}**

**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 mg benzylpenicillin)

**3. TARGET SPECIES**

Cattle and pigs (> 25 kg)

**4. ROUTES OF ADMINISTRATION**

For 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)

**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}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

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

**2. Composition**

**Active substance:**

Benzylpenicillin procaine monohydrate.....300 mg/ml

(corresponding to 170 mg benzylpenicillin)

**Excipients:**

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

White suspension.

**3. Target species**

Cattle and pigs (weighing more than 25 kg).

**4. Indications for use**

For the treatment of systemic infections in cattle 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 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  $\beta$ -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 peni-cillins.

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the 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 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 the target species:

The product is not to be used in pigs weighing less than 25 kg bodyweight.

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:

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction 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 sensitivity 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:

There is no evidence that this veterinary medicinal 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:

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

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):
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Anaphylactic-type reaction <sup>1</sup> , Hypersensitivity reaction <sup>2</sup> , Anaphylactic shock
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1. May be caused by the content of povidone.
2. Penicillins and cephalosporins may cause this following administration of the product. May occasionally be serious.

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):
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Pyrexia <sup>1</sup> , Apathy <sup>1</sup> , Systemic disorder NOS <sup>2</sup> Vomiting <sup>1</sup> Shivering <sup>1</sup> , Incoordination <sup>1</sup> Vaginal discharge <sup>3</sup> Hypersensitivity reaction <sup>4</sup> , Anaphylactic shock
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1. In suckling and fattening pigs which may be caused by the release of procaine
2. Toxic effects have been observed in young piglets, which are transient but can be potentially lethal, especially at higher doses
3. In pregnant sows and gilts could be associated with abortion.
4. Penicillins and cephalosporins may cause this following administration of the product. May occasionally be serious.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## **8. Dosage for each species, routes 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. 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.

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 to avoid underdosing.

## **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)

## **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 31592/5001

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](http://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 representatives and contact details to report suspected adverse reactions:

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

### Contact details to report suspected adverse reactions:

Laboratorios Syva S.A.  
Parque Tecnológico de León  
C/ Nicostrato Vela M15-M16  
24009 León  
Spain  
Tel: + 34 987 800 800  
E-mail: farmacovigilancia@syva.es

## **17. Other information**

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*Gavin Hall*  
Approved: 10 November 2025