

**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 and pigs  
Procaine benzylpenicillin

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:  
Benzylpenicillin procaine monohydrate 300 mg  
(corresponding to 170 mg benzylpenicillin)

### **3. PHARMACEUTICAL FORM**

Suspension for injection  
White suspension

### **4. PACKAGE SIZE**

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

### **5. TARGET SPECIES**

Cattle 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)

## **9. SPECIAL WARNINGS, IF NECESSARY**

Read the package leaflet before use.

## **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 2°C-8°C.

## **11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator

Keep the vial 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 31592/5001

**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/ml suspension for injection for cattle and pigs.  
Procaine benzylpenicillin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:  
Benzylpenicillin procaine monohydrate.....300 mg  
(corresponding to 170 mg benzylpenicillin)

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

100 ml  
250 ml

**5. TARGET SPECIES**

Cattle 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)

## **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 2°C- 8°C.

## **11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator

Keep the vial 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

<b>16. MARKETING AUTHORISATION NUMBER</b>
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Vm 31592/5001

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Batch {number}



## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Procactive 300 mg/ml suspension for injection for cattle 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 and pigs.  
Procaine benzylpenicillin

**3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS**

**Active substance:**

Benzylpenicillin procaine  
monohydrate.....300 mg/ml(corresponding to 170 mg  
benzylpenicillin)

**Excipients:**

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

White suspension

**4. INDICATIONS**

For the treatment of systemic infections in cattle and pigs (weighing more than 25 kg) caused by bacteria sensitive to penicillin.

**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 case 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. 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.

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.

## **7. TARGET SPECIES**

Cattle 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.

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)

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store in a refrigerator (2°C-8°C).

Keep the vial 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 2°C-8°C.

## **12. SPECIAL WARNINGS**

Special warnings for each target species:

None

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

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.

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.

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:

Laboratory studies in animals have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

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**

June 2022

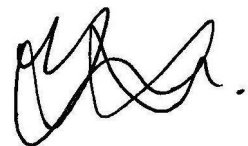
**15. OTHER INFORMATION**

*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: 31592/5001



Approved: 21 September 2023