1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Benzylpenicillin procaine 300 mg
(corresponding to 175.8 mg of benzylpenicillin)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate E218	2.0 mg
Povidone K30	
Sodium citrate	
Disodium edetate	
Lecithin	
Potassium dihydrogen phosphate	
Potassium chloride	
Water for injections	

An off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not inject intravenously.
Do not use in cases of hypersensitivity to penicillin, 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 very small herbivores such as guinea pigs, gerbils and hamsters.
Do not use in the presence of β-lactamase producing pathogens.

3.4 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 and 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 the SPC 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 veterinary medicinal 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 sensitised, 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.
Personal protective equipment consisting of gloves should be worn when handling and administering the veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Uncommon (1 to 10 animals / 1 000 animals treated):	Pyrexia[1], Vomiting[1], Shivering[1], Listless[1], Incoordination[1]
Undetermined frequency (cannot be estimated from the available data)	Systemic disorder[2] , Vaginal discharge[3]

[1] In suckling and fattening pigs, transient
[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

Cattle:

Rare (1 to 10 animals / 10 000 animals treated):	Anaphylactic type reactions[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Allergic reaction[2], Anaphylactic shock[2]

[1] Due to povidone content
[2] To penicillin, may occasionally be serious

Sheep: None known

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 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.

3.8 Interaction with other medicinal products and other forms of interaction

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.
Benzylpenicillin is bactericidal. Avoid concurrent use of bactericidal and bacteriostatic antibiotics as they can antagonise the bactericidal effect of penicillins.

3.9 Administration routes and dosage

Intramuscular use.

Dosage: 12 mg procaine benzylpenicillin (corresponding to 7 mg benzylpenicillin) per kg bodyweight (equivalent to 2 ml of the veterinary medicinal product per 50 kg bw) per day.
The treatment duration is 3 to 7 days.
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.
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.
Before use, shake the vial gently for a minimum of 10 seconds until all sediment is readily dispersed.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 10 days for treatment duration 3 days.
12 days for treatment duration 4-7 days.
Milk: 108 hours (4.5 days).

Pigs:
Meat and offal: 7 days for treatment duration 3 days.
9 days for treatment duration 4-7 days.

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

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01CE09

4.2 Pharmacodynamics

Procaine benzylpenicillin is a complex, sparingly soluble organic salt of benzylpenicillin.
Benzylpenicillin exerts its effect on multiplying bacteria by blocking the biosynthesis of the bacterial wall.

Penicillin is a β-lactam antibiotic which has bactericidal activity against mainly Gram-positive bacteria and some Gram-negative organisms susceptible to penicillin.
Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas* spp. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

Resistance to benzylpenicillin is recognised to occur in some isolates of pathogens for which this veterinary medicinal product is indicated. The most common resistance mechanism is the veterinary medicinal production of β-lactamase enzyme. Resistance may also result from alterations to penicillin binding proteins (PBP).

There is cross-resistance between penicillins and other beta-lactam antibiotics. Where a pathogen has acquired penicillin resistance by the transfer of mobile genetic elements, co-resistance to other antimicrobial classes may also be present.

4.3 Pharmacokinetics

Following intramuscular injection of the veterinary medicinal product, peak concentrations of penicillin in plasma are reached within 1 to 2 hours.
Use of the procaine salt is intended to delay absorption of the drug from the injection site and to give rise to a longer duration of action.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is packaged in clear 100 ml Type I and 250 ml clear Type III glass vials sealed with red or grey, siliconised bromobutyl rubber stoppers and aluminium overseal, containing a sterile aqueous suspension.
Carton box with 1 vial of 100 ml
Carton box with 1 vial of 250 ml
12 shrink-wrapped boxes containing 1 vial of 100 ml
12 shrink-wrapped boxes containing 1 vial of 250 ml
Carton box with 48 boxes containing 1 vial of 100 ml
Carton box with 48 boxes containing 1 vial of 250 ml
The vials are colourless.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/076/001

8. DATE OF FIRST AUTHORISATION

18/06/2021

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

18/02/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).