Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampitras 20% w/v, suspension for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Ampicillin 200mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oily, white suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment of acute infections of the gastrointestinal, urinary and respiratory tract; infections of the skin and soft tissues; septicemia and polyarthritis in the new-born.

4.3 Contraindications

Do not use in rabbits and other rodents.

Do not use in horses.

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Shake well before use.
Avoid the introduction of contamination before use.
Should any apparent growth or discolouration occur, the product should be discarded.
Transitory local swelling may occur. It is advisable not to inject too large a volume at the same injection site. It is advisable to alternate injection sites for consecutive injections.

Special precautions to be taken by the person administering the 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 can 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.

4.6 Adverse reactions (frequency and seriousness)

Transitory local swelling may occur.

Allergic reactions in animals hypersensitive to penicillins.

4.7 Use during pregnancy, lactation or lay

None known.

4.8 Interaction with other medicinal products and other forms of interaction

Possible antagonism with principally bacteriostatic antibiotics (e.g. tetracyclines).

4.9 Amounts to be administered and administration route

For intramuscular injection.

Dosage: 5-10mg/kg, equivalent to 2.5-5ml/100kg bodyweight twice daily for 3-5 days.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Ampicillin is markedly free of direct toxic effects even at doses many times in excess of the recommended treatment dose. Treatment of anaphylaxis: adrenalin and/or glucocorticoids i.v.. Other forms of allergy: antihistamines and/or corticosteroids.

4.11 Withdrawal Period(s)

Meat: 40 days. Animals intended for human consumption may be slaughtered from 40 days following the last treatment.

Milk: 7 days. Milk intended for human consumption may be taken from treated animals 7 days (i.e. at the 15th milking) following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, penicillins with extended spectrum
ATCvet Code: QJ01CA01

5.1 Pharmacodynamic properties

Ampicillin is a semi-synthetic derivative of penicillin. It has a broader spectrum because it is active against many Gram-positive and Gram-negative germs, i.e. *Streptococcus spp., penicillinase negative Staphylococcus spp., Corynobacterium spp., Clostridium spp., Fusobacterium spp., Hemophilus spp., Brucella spp.*

The bacteria are very susceptible to ampicillin during the stage of active multiplication. This results in a therapeutic application of AMPITRAS 20% to acute infections.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium-chain triglycerides

6.2 Incompatibilities

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

6.3 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

6.4 Special precautions for storage

Do not store above 25^{o}C. Protect from light.

6.5 Nature and composition of immediate packaging

A 100 ml uncoloured Type III glass vial, closed with a butyl rubber stopper.

The vials are packed in a polystyrene box, 12 vials of 100 ml per box, with 12 package leaflets.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under nation waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Kela N.V.,
St. Lenaartseweg 48,
2320 Hoogstraten,
Belgium.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10981/006/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 1987

10 DATE OF REVISION OF THE TEXT

June 2012