SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amfipen LA 100 mg/ml suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each ml contains:
Ampicillin (as anhydrous ampicillin) 100 mg

Excipient:
Dodecyl gallate 87.5 µg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
White to off white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, pigs, dogs and cats.

4.2 Indications for use, specifying the target species

Amfipen LA is indicated for treatment of diseases or secondary infections due to the following bacteria sensitive to ampicillin in dogs, cats, cattle, sheep and pigs and where prolongation of activity from a single injection is required: Streptococcus spp., *Trueperella pyogenes*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Erysipelothrix rhusiopathiae*, *Staphylococcus aureus* and *Staphylococcus species*.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance, or to any of the excipients.
Do not administer to rabbits, hamsters or guinea pigs.
Not effective against beta-lactamase producing organisms.
Do not use this product in horses due to the likelihood of severe local reaction at the injection site.
Do not inject dogs and cats intramuscularly.
Do not use in animals producing milk for human consumption.

4.4 Special warnings for each target species

Severe disturbances of the intestinal bacterial flora of herbivores may occur.

4.5 Special precautions for use

i) Special precautions for use in animals
Whenever possible, the product should only be used based on susceptibility testing.
Official and local antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to ampicillin and may decrease the effectiveness of treatment with other beta-lactams due to the potential for cross-resistance.

ii) Special precautions for 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 reactions to cephalosporins and vice versa. Allergic reactions 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 or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Severe disturbances of the intestinal bacterial flora of herbivores may occur.
Allergies to ampicillin can occur rarely. Local swelling at the injection site may occur in dogs, this usually regresses spontaneously in 2-4 days.

4.7 Use during pregnancy, lactation or lay

No special precautions necessary.

4.8 Interaction with other medicinal products and other forms of interaction

Bacteria, particularly gram-negative organisms, that show a cross-resistance with other ß lactam antibiotics may show resistance.

There is antagonism between this product and antibiotics with bacteriostatic activity.

4.9 Amount(s) to be administered and administration route

Dosage:
Cattle and sheep 15 mg/kg, pigs 25 mg/kg by intramuscular route.
Dogs 15 mg/kg, cats 20 mg/kg by subcutaneous route.
e.g.

Cow	500 kg	75 ml
Sheep	50 kg	7.5 ml
Pig	50 kg	12.5 ml
Dog	10 kg	1.5 ml
Cat	5kg	1 ml

Shake well before use. Clean the area of the injection site and swab with spirit. This product does not contain an antimicrobial preservative.
Only dry sterile needles and syringes should be used for administration and the septum should be swabbed before removing each dose. Do not use the same injection site more than once during a course of treatment. Do not administer more than 10 ml per injection site in pigs and sheep and 20 ml in cattle. Treatment may be repeated once after 48 hours.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

Ampicillin is a compound with a very high therapeutic ratio. It is unlikely that an overdose of Amfipen LA will have adverse effects on the treated animal. No specific antidote or treatment is recommended.

4.11 Withdrawal period(s)

Meat and offal
Cattle, pigs and sheep: 60 days

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, β-lactam antibacterials, enicillins, penicillins with extended spectrum.
ATC Vet Code: QJ01CA01.

5.1 Pharmacodynamic properties

Ampicillin is a beta-lactam antibiotic which has bactericidal activity against mainly Gram-positive bacteria and some Gram-negative aerobes. It is sensitive to beta-lactamase (penicillinase) inactivation. It is widely distributed in the

extracellular fluids after absorption, and eliminated almost entirely by the kidneys.
Bioavailability studies indicate that a minimum duration of activity of 48 hours can be expected following a single injection.

5.2 Pharmacokinetic particulars

Amfipen LA, containing ampicillin anhydrate in a long acting base, has been especially developed to overcome the disadvantage of frequent administrations required for short-acting ampicillin formulations. Blood level studies clearly show that the injection interval can be extended to at least 48 hours instead of the usual 12-24 hours.
After an initial peak at one hour after injection, the ampicillin concentrations decline slowly and gradually over the 48 hour period and 34 to 50 % of the ampicillin becomes available on the second day after injection.
Animal studies have demonstrated that ampicillin is evenly distributed throughout the body tissues and is concentrated in the liver and the kidneys. It is excreted unchanged in the urine. Investigations have shown that ampicillin is excreted in high concentration in the bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dodecyl gallate
Aluminium monostearate
Fractionated coconut oil

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Type II (Ph Eur) glass vials closed with halogenated butyl rubber stoppers or PET vials closed with halogenated butyl rubber stoppers. The both types of vial are sealed with an aluminium cap. The vials contain 80 ml of product.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4233

9. DATE OF FIRST AUTHORISATION

29 August 1991

10. DATE OF REVISION OF THE TEXT

June 2021

Approved: 09/06/21