SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen LA 150 mg/ml, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Amoxicillin (as Amoxicillin Trihydrate) 150 mg

Excipients:
Butylated hydroxytoluene 0.08 mg
Butylated hydroxyanisole 0.08 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
An off-white oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, pigs, cats and dogs.

4.2 Indications for use, specifying the target species

The product is suitable for the control of infections, due to susceptible micro-organisms, in cattle, pigs, sheep, dogs and cats where a single injection giving prolonged antibiotic cover is required. It may also protect from secondary bacterial invasion in cases where bacteria are not the initial cause of the disease.

Indications include infections of:
Alimentary tract, Respiratory tract, Skin and soft tissue
Urogenital tract and in prevention of post-operative infection (treat before surgery).

In vitro amoxicillin is effective against a wide range of Gram-positive and Gram-negative bacteria which include:
Escherichia coli, Klebsiella pneumonia, *Proteus* spp., *Salmonella* spp. staphylococci and streptococci.

4.3 Contra-indications

This product is not suitable for administration via intravenous or intrathecal routes.
Not to be administered to animals sensitive to penicillin.
Not to be used in rabbits, guinea pigs, hamsters, gerbils or in any other small herbivores.

Not effective against beta-lactamase producing organisms.

4.4 Special warning for each target species

Not to be used in animals with previous sensitivity to penicillins.

4.5 Special precautions for use

(i) Special precautions for use in animals

None

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may cause 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.
   Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic reactions were reported in very rare cases during post-marketing surveillance. In the case of allergic reactions, treatment should be discontinued and symptomatic treatment should be initiated.
Local tissue reactions may be observed in very rare cases during post-marketing surveillance.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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).

4.7 Use during pregnancy, lactation or lay

No special precautions necessary.

4.8 Interaction with other medicinal products and other forms of interaction

Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (tetracyclines, chloramphenicol) which inhibit multiplication. Synergism occurs with ß-lactam antibiotics and aminoglycosides.

4.9 Amounts to be administered and administration route

Dosage: in general, 15 mg/kg bodyweight, repeated if necessary after 48 hours.
Dose volume is equivalent to 1 ml per 10 kg body weight. If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided into two or more sites.
A separate injection site should be used for each administration.

Suggested doses are:

Cattle	500 kg	- 50	ml
Sheep	50 kg	- 5	ml
Pigs	50 kg	- 5	ml
Dogs	10 kg	- 1	ml
Cats	5 kg	- 0.5	ml

Administration: Cattle, sheep and pigs - by intramuscular injection only. Dogs and cats - intramuscular or subcutaneous injection. To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid underdosing. An appropriately graduated syringe must be used to ensure accurate administration of the required dose volume. This is particularly important when injecting small volumes.
Shake the vial before use. As with other injectable preparations, normal aseptic precautions should be observed as this product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe. After administration massage the injection site.
If no distinct clinical response is observed after the second treatment, a reassessment of the diagnosis and a change of treatment may be required.

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

Amoxicillin is a compound with a very high therapeutic ratio. It is very unlikely that an overdose of Amoxypen LA will have adverse effects on the treated animal.

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

Cattle:
Meat and offal: 39 days
Milk: 108 hours (4.5 days)

Pigs:
Meat and offal: 42 days

Sheep:
Meat and offal: 29 days
Milk: Not authorised for use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials, penicillins

ATC Vet Code: QJ01CA04

5.1 Pharmacodynamic properties

The active ingredient, amoxicillin, is a bactericidal antibiotic of the ß-lactam class which acts by inhibition of bacterial cell wall synthesis. Amoxicillin is not resistant to the action of beta-lactamases which can hydrolyse the molecules causing the beta-lactam ring structure to open, rendering it antibiotically inactive.

Due to its wide distribution after absorption, high levels of amoxicillin are found in kidney, urine, liver and bile.

5.2 Pharmacokinetic particulars

Following intramuscular injection in cattle at the recommended dosage rate, peak levels were observed 2.98 hours following administration

Following intramuscular injection in sheep at the recommended dosage rate, peak levels were observed 0.96hours following administration

Following intramuscular injection in pigs at the recommended dosage rate, peak levels were observed 1.18 hours following administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated hydroxytoluene
Butylated hydroxyanisole
Aluminium stearate
Propylene Glycol Dicaprylocaprate

6.2 Major incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.
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

Multidose vials (Glass Type III Ph. Eur or Type II Ph. Eur.) of 100 ml fitted with nitrile rubber bungs and aluminium unlacquered caps.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4340

9. DATE OF FIRST AUTHORISATION

26 January 1996

10. DATE OF REVISION OF TEXT

December 2021

Approved 15 December 2021