SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen Injection 150 mg/ml, suspension for injection

2. NAME AND PROPORTION OF EACH ACTIVE SUBSTANCE, AND OF ANY EXCIPIENT, IF KNOWLEDGE OF THE EXCIPIENT IS NEEDED FOR SAFETY REASONS

Active substance per ml:

Amoxicillin (as Amoxicillin Trihydrate)	150 mg

Antioxidant preservatives per ml:

Butylated hydroxytoluene	0.08 mg
Butylated hydroxyanisole	0.08 mg

See full list of excipients in 6.1

3. PHARMACEUTICAL FORM

Off-white, sterile, non-aqueous suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, pigs, cats and dogs

4.2 Indications for use, specifying the target species

For the treatment of infections caused by a wide range of Gram-positive and Gram-negative bacteria which include:
Actinobacillus equuli, *Actinobacillus lignieresi, Actinomyces bovis, Bacillus anthracis, Bordetella bronchiseptica,*Clostridium spp.Corynebacterium spp., *Erysipelothrix rhusiopathiae,Escherichia coli,* Fusiformis spp.*,* Haemophilus spp.*,* Moraxella spp.*,* Mannheimia spp. *Proteus mirabilis*, 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)

Occasional local tissue reaction may result from use of this product.

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 beta-lactam antibiotics and aminoglycosides.

4.9 Amounts to be administered and administration route

Dosage: in general 7 mg/kg bodyweight (equivalent to 0.5 ml per 10 kg), once daily for up to five days.
Suggested doses are:

Cattle	500 kg	- 25.0 ml
Sheep	50 kg	- 2.5 ml
Pigs	50 kg	- 2.5 ml
Dogs	10 kg	- 0.5 ml
Cats	5 kg	- 0.25 ml

Administration: Cattle, sheep and pigs - by intramuscular injection only. Dogs and cats – intramuscular or subcutaneous injection. 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. 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. Treatment should normally be repeated at 24 hour intervals depending on clinical response. A separate injection site should be used for each administration and not more than 20 ml should be injected at one site (see also 4.3).

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 Injection 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

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may be taken only after 24 hours from the last treatment. Not for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 18 days from the last treatment, sheep may be slaughtered for human consumption only after 10 days from the last treatment and pigs may be slaughtered for human consumption only after 16 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredient, amoxicillin, is a bactericidal antibiotic of the beta-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.
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5.2 Pharmacokinetic particulars

Following intramuscular injection in cattle at the recommended dosage rate peak levels were observed 2.37 hours following final administration

Following intramuscular injection in sheep at the recommended dosage rate peak levels were observed 1.75hours following final administration

Following intramuscular injection in pigs at the recommended dosage rate peak levels were observed 2.0 hours following final 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, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time

Shelf life: 12 months
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material safely

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 clear glass vials (Type II or Type III 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 01708/4339

9. DATE OF FIRST AUTHORISATION

26 January 1996

10. DATE OF REVISION OF TEXT

March 2021

Approved 12 March 2021