PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amfipen LA 100 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ampicillin (as anhydrous ampicillin) 100 mg/ml

Also contains dodecyl gallate 87.5 µg/ml as an antioxidant preservative

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

80 ml

5. TARGET SPECIES

Cattle, sheep, pigs, dogs and cats.

6. INDICATION(S)

Not required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection for use in cattle, sheep and pigs.

Subcutaneous injection for use in dogs and cats.

To be used in accordance with the directions of a veterinary surgeon.

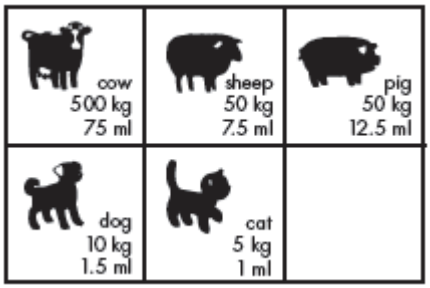
Shake well before use.

Swab septum before removing each dose.

Use a dry sterile needle and syringe.

Following removal of first dose use within 28 days.

Maximum dose volume at any one injection site: Pigs, sheep = 10 ml Cattle= 20 ml.



8. WITHDRAWAL PERIOD

Withdrawal periods:

Meat and offal: Cattle, sheep and pigs 60 days.

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Penicillins/cephalosporins may occasionally cause severe allergic reactions.

Wash hands after use.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Do not freeze.

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

Distributor in N. Ireland:

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

DUBLIN 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4233

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amfipen LA 100 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ampicillin (as anhydrous ampicillin) 100 mg/ml

Also contains dodecyl gallate 87.5 µg/ml as an antioxidant preservative

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

80 ml

5. TARGET SPECIES

Cattle, sheep, pigs, dogs and cats.

6. INDICATION(S)

Not required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM (cattle, sheep, pig) or SC (dog, cat)

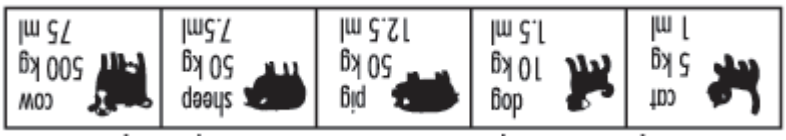
Shake well before use.

Swab septum before removing each dose.

Use a dry sterile needle and syringe.

Following removal of first dose use within 28 days.

Maximum dose volume at any one injection site: Pigs, sheep = 10 ml Cattle= 20 ml.



8. WITHDRAWAL PERIOD

Withdrawal periods:

Meat and offal: Cattle, sheep and pigs 60 days.

Not authorised for use in animals producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Penicillins/cephalosporins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

Exp:

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Do not freeze.

Keep the container in the carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4233

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR:

Amfipen LA 100 mg/ml suspension for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

Buckinghamshire

MK7 7AJ

Manufacturer responsible for batch release:

Intervet Productions
Via Nettunense km 20,300
04011 Aprilia (LT)
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amfipen LA 100 mg/ml suspension for injection.

Ampicillin.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains 100 mg ampicillin, as anhydrous ampicillin.

Also contains 87.5 µg/ml dodecyl gallate as an antioxidant preservative.

White to off white suspension.

4. INDICATION(S)

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 spp*.

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

For use in cattle, sheep, pigs, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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	5 kg	1 ml

9. ADVICE ON CORRECT ADMINISTRATION

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

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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Cattle, pigs and sheep: 60 days.

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “Exp”. The expiry date refers to the last day of that month.

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening of the immediate packaging: 28 days.

When the container is broached / opened for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

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 this leaflet 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.

Special precautions to be taken by 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.

Pregnancy, Lactation and Lay:

No special precautions necessary.

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.

Overdose (symptoms, emergency procedures, antidotes):

It is unlikely that an overdose of Amfipen LA will have adverse effects on the treated animal. No specific antidote or treatment is recommended.

Incompatibilities:

Do not mix this product with any other veterinary medicinal product.

For Animal Treatment Only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

Bioavailability studies indicate that a minimum duration of activity of 48 hours can be expected following a single injection.

Amfipen LA is supplied in either glass or PET vials closed with rubber stoppers. Both types of vial are sealed with an aluminium cap. Each vial contains 80 ml of Amfipen LA.

POM-V
To be supplied only on veterinary prescription.

MA number:

Vm 01708/4233.

Distributor in Northern Ireland:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24.

Approved: 09/06/21