PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen® LA 150 mg/ml, suspension for injection
Amoxicillin

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin (as Trihydrate) 150 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

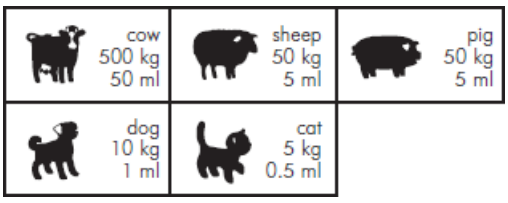
5. TARGET SPECIES

Cattle, sheep, pigs, cats and dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M./S.C.
Shake the vial before use
Cattle, sheep and pigs – By intramuscular injection only.
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 and injected into two or more sites.



Swab the septum before removing each dose.
Use a dry, sterile needle and syringe.

8. WITHDRAWAL PERIOD

Withdrawal periods:
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.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information and warnings before use.
Penicillins/cephalosporins may occasionally cause severe allergic reactions.
See insert for user warnings**.**

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.
Keep the container in the outer carton.
Once broached, use within 28 days.
Use by……

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

Discard unused contents.

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

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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 Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4340

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen® LA 150 mg/ml, suspension for injection
Amoxicillin

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin (as Trihydrate) 150 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep, pigs, cats and dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M./S.C.

Cattle, sheep and pigs – By intramuscular injection only.

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 andinjected into two or more sites.

Shake the vial before use

Swab the septum before removing each
dose.Use a dry, sterile needle and syringe.
Avoid the introduction of contamination during use.

8. WITHDRAWAL PERIOD

Withdrawal periods: 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings**.**

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Keep the vial in the outer carton. Once broached use within 28 days.

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

Read package leaflet before use.

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

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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 01708/4340

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR:

AMOXYPEN® LA 150 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

MA Holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen LA 150 mg/ml, suspension for injection
Amoxicillin

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

Amoxypen LA is an off-white, sterile, non-aqueous suspension for injection containing 150 mg amoxicillin (as Amoxicillin Trihydrate) per ml.

4. INDICATION(S)

Amoxicillin is a broad-spectrum, bactericidal antibiotic. Amoxypen LA is indicated for the treatment of infections caused by micro-organisms sensitive to amoxicillin in cattle, sheep, pigs, dogs and cats where prolonged antibiotic cover from a single injection is required.

In vitro, amoxicillin is active against a wide range of both Gram-positive and Gram-negative organisms including: *Escherichia coli, Klebsiella pneumoniae, Proteus* spp., *Salmonella* spp. staphylococci and streptococci. Particular clinical indications include infections of the gastro-intestinal, respiratory and urogenital tracts, skin and soft tissue infections, secondary bacterial infections in viral or parasitic diseases and where postoperative antibiotic cover is required.

5. CONTRAINDICATIONS

Do not administer via intravenous or intrathecal routes.

Amoxypen LA should not be administered to animals sensitive to penicillin.

As with other penicillins, amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters, gerbils or in any other very small herbivores.

Not effective against beta-lactamase producing organisms.

6. ADVERSE REACTIONS

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).

7. TARGET SPECIES

Cattle, sheep, pigs, dogs and cats

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

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.

Cattle, sheep and pigs - by intramuscular injection only.

Dogs and cats - intramuscular or subcutaneous injection.

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

9. ADVICE ON CORRECT ADMINISTRATION

After administration massage the injection site. 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.
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.
If no distinct clinical response is observed after the second treatment, a reassessment of the diagnosis and a change of treatment may be required.

10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Shake the vial before use.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after <Expiry>. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 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 should be discarded should be worked out. This discard date should be written in the space provided on the carton.

Keep container in outer carton.

12. SPECIAL WARNING(S)

Operator warnings:

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 sensitized, 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.

FOR ANIMAL TREATMENT ONLY. KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2021

15. OTHER INFORMATION

Following parenteral administration, amoxicillin is widely distributed and high levels are seen particularly in kidney, urine, liver and bile.

DISTRIBUTION CATEGORY

POM-V To be supplied only on veterinary prescription.

MARKETING AUTHORISATION NUMBER

Vm 01708/4340
UK authorised veterinary medicinal product.

PACKAGE QUANTITIES
Multidose vials of 100 ml

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 15 December 2021