# PARTICULARS TO APPEAR ON THE OUTER PACKAGE
# CARTON BOX

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen® Injection 150 mg/ml, suspension for injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

AMOXICILLIN (as Trihydrate) 150 mg/ml

## 3. PHARMACEUTICAL FORM

Non-aqueous suspension for injection for the treatment of cattle, sheep, pigs, cats and dogs.

## 4. PACKAGE SIZE

100 ml

## 5. TARGET SPECIES

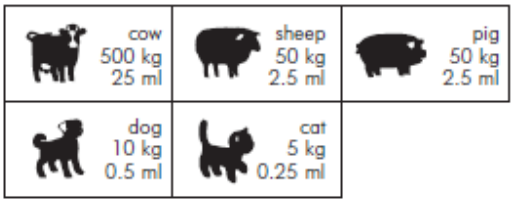
Non-aqueous suspension for injection for the treatment of cattle, sheep, pigs, cats and dogs.

## 6. INDICATION(S)

*[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]*

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M./S.C.
Shake the vial before use




Swab the septum before removing each dose.
Use a dry, sterile needle and syringe.
Following withdrawal of the first dose use within 28 days.

## 8. WITHDRAWAL PERIOD

Withdrawal periods:
Milk: (Cows only) 24 hours
Meat: Cattle 18 days

Sheep 10 days
Pigs 16 days

## 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 leaflet for user warnings**.**

## 10. EXPIRY DATE

Lot/Expiry date:

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store out of light.

Keep the container in the outer carton.

## 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.

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

FOR ANIMAL TREATMENT ONLY KEEP OUT OF REACH AND SIGHT 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

Distributed in Northern Ireland by:
INTERVET IRELAND Ltd.
Magna Drive
Magna Business Park
Citywest Road
DUBLIN 24

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4339
UK authorised veterinary medicinal product.

## 17. MANUFACTURER'S BATCH NUMBER

Lot/Expiry date:

# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen® Injection 150 mg/ml, suspension for injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

AMOXICILLIN (as Trihydrate) 150 mg/ml

## 3. PHARMACEUTICAL FORM

Non-aqueous suspension for injection for the treatment of cattle, sheep, pigs, cats and dogs.

## 4. PACKAGE SIZE

100 ml

## 5. TARGET SPECIES

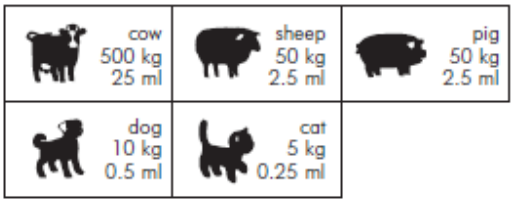
Non-aqueous suspension for injection for the treatment of cattle, sheep, pigs, cats and dogs.

## 6. INDICATION(S)

*[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]*

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M./S.C.
Shake the vial before use. Keep vial in outer carton.




Swab the septum before removing each dose.
Use a dry, sterile needle and syringe.
Following withdrawal of the first dose use within 28 days.

## 8. WITHDRAWAL PERIOD

Withdrawal periods:
Milk: (Cows only) 24 hours
Meat: Cattle 18 days

Sheep 10 days
Pigs 16 days

## 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 leaflet for user warnings**.**

## 10. EXPIRY DATE

Use by:
Expiry:

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store out of light.

Keep vial in outer carton.

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

Read package leaflet for further information, warnings and disposal advice 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.

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

FOR ANIMAL TREATMENT ONLY KEEP OUT OF REACH AND SIGHT 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

Distributed in Northern Ireland by:
INTERVET IRELAND Ltd.
Magna Drive
Magna Business Park
Citywest Road
DUBLIN 24

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4339
UK authorised veterinary medicinal product.

## 17. MANUFACTURER'S BATCH NUMBER

Batch No.:

**[Include information under these headings as it appears in the SPC]**
**PACKAGE LEAFLET FOR:**
**AMOXYPEN® INJECTION 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

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

Manufacturer responsible for batch release:
Norbrook Laboratories Ltd
Station Works
Camlough Road
Newry
Co Down
BT35 6JP

Distributed in Northern Ireland by:
INTERVET IRELAND Ltd.
Magna Drive
Magna Business Park
Citywest Road
DUBLIN 24

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxypen® Injection 150 mg/ml, suspension for injection

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

Amoxypen Injection 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 Injection is indicated for the treatment of infections caused by micro-organisms sensitive to amoxicillin in cattle, sheep, pigs, dogs and cats. *In vitro,* amoxicillin is active against a wide range of both Gram-positive and Gram-negative organisms including: *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.

## 5. CONTRAINDICATIONS

Do not administer via intravenous or intrathecal routes.
Amoxypen Injection 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 or gerbils. Caution is advised when used in any other very small herbivores.
Not effective against beta-lactamase producing organisms.
Allergies to amoxicillin can occur rarely.
Occasional local tissue reactions may occur following the use of this product.

## 6. ADVERSE REACTIONS

Allergies to amoxicillin can occur rarely.
Occasional local tissue reactions may occur following the use of this product.

## 7. TARGET SPECIES

Amoxicillin is a broad-spectrum, bactericidal antibiotic. Amoxypen Injection is indicated for the treatment of infections caused by micro-organisms sensitive to amoxicillin in cattle, sheep, pigs, dogs and cats.

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

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 (max 20 ml at one site)
Sheep 50 kg - 2.5 ml
Pigs 50 kg - 2.5 ml
Dogs 10 kg - 0.5 ml
Cats 5 kg - 0.25 ml

## 9. ADVICE ON CORRECT ADMINISTRATION

*Administration*: Cattle, sheep and pigs - by intramuscular injection only. Dogs and cats - intramuscular or subcutaneous injection. Normal aseptic precautions should be observed. After administration massage the injection site. An appropriately graduated syringe must be used to ensure accurate administration of the required dose volume. This is particularly important when injecting small volumes. A separate injection site should be used for each administration.

## 10. WITHDRAWAL PERIOD(S)

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.
Pigs may be slaughtered for human consumption only after 16 days from the last treatment.
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.

## 11. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL PRECAUTIONS
Do not store above 25°C. Protect from light. Shake the vial before use. Swab the septum before removing each dose. In common with other oil-based suspensions this product does not contain an antimicrobial preservative. Only dry, sterile needles and syringes should be used for administration. Following withdrawal of the first dose, use the product within 28 days. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. 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 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. Keep container in outer carton.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

## 15. OTHER INFORMATION

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

LEGAL CATEGORY

POM-V

To be supplied only on veterinary prescription.

MARKETING AUTHORISATION NUMBER
Vm 01708/4339
UK authorised veterinary medicinal product.

PACKAGE QUANTITIES
Multidose vials of 100 ml

Approved 12 March 2021