

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**CARTON BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Amoxyphen® 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

 cow 500 kg 25 ml	 sheep 50 kg 2.5 ml	 pig 50 kg 2.5 ml
 dog 10 kg 0.5 ml	 cat 5 kg 0.25 ml	

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**

Amoxyphen® 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.

 cow 500 kg 25 ml	 sheep 50 kg 2.5 ml	 pig 50 kg 2.5 ml
 dog 10 kg 0.5 ml	 cat 5 kg 0.25 ml	

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 lignieresii*, *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

A handwritten signature in black ink, appearing to read "A. Hunter.", positioned below the approval date.