

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl™ Long Acting 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml suspension contains 150 mg amoxicillin as a long acting formulation of Amoxicillin trihydrate in an oily base.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cat, dog, sheep

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial well before use.

The recommended dosage rate is 15 mg/kg which is equivalent to 1.0 ml/10 kg bodyweight. For subcutaneous or intramuscular injection in cats & dogs and intramuscular injection only in sheep.

5 kg	20 kg	65 kg
		
cat	dog	sheep
0.5 ml	2 ml	6.5 ml

If the volume to be given is greater than 5 ml, it should be divided and injected into two separate sites.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 45 days. Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

User warning: Penicillins/cephalosporins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not broach more than 40 times.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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

Disposal: read package leaflet

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

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Clamoxyl is a trademark owned by, and used under licence from, Glaxo Group Limited.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4013

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (OUTER LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl™ Long Acting 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 150 mg amoxicillin as a long acting formulation of **Amoxicillin trihydrate** in an oily base.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

6 vials x 100 ml

5. TARGET SPECIES

Cat, dog, sheep

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial well before use.

The recommended dosage rate is 15 mg/kg which is equivalent to 1.0 ml/10 kg bodyweight.

For subcutaneous or intramuscular injection in cats & dogs and intramuscular injection only in sheep.

5 kg	20 kg	65 kg
		
cat	dog	sheep
0.5 ml	2 ml	6.5 ml

If the volume to be given is greater than 5 ml, it should be divided and injected into two separate sites.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 45 days.

Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

User warning: Penicillins/cephalosporins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not broach more than 40 times.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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

Disposal: read package leaflet

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

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

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4013

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR:

Clamoxyl™ Long Acting 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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22

[Batch release site not currently stated]

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl Long Acting 150 mg/ml suspension for injection

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

CLAMOXYL L.A. Injection is an off-white oily suspension containing 150 mg/ml amoxicillin as Amoxicillin trihydrate.

The formulation is designed to provide effective antibiotic activity over a period of 48 hours.

Chemically amoxicillin is: 6(D(-) - α - amino-p-hydroxyphenylacetamido) penicillanic acid.

4. INDICATION(S)

CLAMOXYL is a broad spectrum semi-synthetic penicillin which is bactericidal, in vitro, against a wide range of Gram-positive and Gram-negative bacteria, including the following:

Gram Negative

Actinobacillus lignieresii
Bordetella bronchiseptica
Escherichia coli
Fusiformis spp.
Haemophilus spp.
Moraxella spp.
Pasteurella spp.
Proteus mirabilis
Salmonella spp.

Gram Positive

Bacillus anthracis
Clostridium spp.
Corynebacterium spp.
Erysipelothrix rhusiopathiae
Streptococci
Staphylococci
(penicillin-sensitive strains)

Since animals are normally dosed relatively infrequently, the speed of action of an antibiotic following each administration is obviously important. *In vitro* and *in vivo* trials

demonstrate that amoxicillin kills bacteria more rapidly than all other antibiotics tested. This speed of action is of particular value when animals are at risk or distressed.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

For the control of infections caused by susceptible organisms in sheep, dogs and cats where prolonged activity from a single injection is required. It may also be used to control secondary bacterial invasion in conditions where bacteria are not a primary cause of disease.

Particular indications for CLAMOXYL L.A. are:

- 1) Alimentary tract infections, including enteritis.
- 2) Respiratory tract infections.
- 3) Urogenital tract infections including cystitis and metritis.
- 4) Skin and soft tissue infections, including wounds, abscesses, foot infections, joint and navel ill.
- 5) Prevention of post-operative infections by injection prior to surgery.

5. CONTRAINDICATIONS

Do not use in animals with known sensitivity to the active substance.

6. ADVERSE REACTIONS

Use of the product may occasionally result in local tissue reaction.

In common with all other penicillins, amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores.

Penicillins and cephalosporins may cause hypersensitivity (allergy, allergic skin reactions) after use. Allergic reactions may occasionally be serious (anaphylaxis).

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

Cats, dogs, sheep

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

The recommended dosage rate is 15 mg/kg bodyweight. If necessary, the dose may be repeated after 48 hours.

The following is intended as a guide:

Animal	Specimen weight kg	Dose volume
Sheep	65	6.5 ml
Lamb	10	1.0 ml
Dog – large	35	3.5 ml
– medium	20	2.0 ml
– small	10	1.0 ml
Cat	5	0.5 ml
The recommended dose is equivalent to 1.0 ml per 10 kg bodyweight.		

Inject by the subcutaneous or intramuscular route (dogs and cats) or the intramuscular route only (sheep), then massage the injection site.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial well before use. (For ease of administration in dogs and cats, needles no finer than 20 gauge should be used). If the volume to be given is greater than 5 ml it should be divided and injected into two separate sites. The suspension is not suitable for intravenous or intrathecal administration.

Use a new anatomical site for repeated injections.

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

10. WITHDRAWAL PERIOD(S)

Meat and offal: 45 days.

Not for use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Do not broach more than 40 times.

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

This product does not contain an antimicrobial preservative, following withdrawal of the first dose, use the product within 28 days. Discard unused material.

To avoid excessive perforation damage to the rubber seal, it is recommended that the 250 ml vial be used for large animal treatment only.

12. SPECIAL WARNING(S)

In common with other penicillin preparations, hydrolysis takes place rapidly in the presence of water. It is important, therefore, that a dry syringe is used when extracting suspension for injection, to avoid contaminating the remaining contents of the vial with drops of water.

Special warnings for each target species

The product is not effective against beta-lactamase producing organisms.

Complete cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins.

Use of the product/amoxicillin should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.

User warnings

Care should be taken to avoid accidental self-injection.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure taking all recommended precautions.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Keep out of the sight and reach of children.

For animal treatment only.

Interaction with other medicinal products and other forms of interaction

It is not generally recommended to use bactericidal and bacteriostatic antibiotics at the same time.

Beta-lactam antibiotics are known to interact with antibiotics with bacteriostatic action such as chloramphenicol, macrolides, sulfonamides and tetracyclines. There is also synergic action of penicillins with aminoglycosides.

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

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

April 2022

15. OTHER INFORMATION

Clamoxyl L.A. Injection is available in 100 ml and 250 ml vials.

Not all pack sizes may be marketed.

FURTHER INFORMATION

The following features of CLAMOXYL L.A. Injection warrant special mention:

1. After absorption, amoxicillin is widely distributed throughout body tissues, with especially high levels in the kidneys, urine, liver and bile.
2. In respiratory infections, amoxicillin crosses inflamed pulmonary membranes into mucus. As the disease responds and associated inflammation recedes, amoxicillin levels are maintained in the mucus thus preventing recrudescence of the original infection.
3. Also of importance is the very rapid bactericidal action (e.g. *E. coli* are completely lysed by 10 mcg/ml of amoxicillin in only one hour, in vitro).
4. Amoxicillin shares with other penicillins the virtual absence of toxicity problems even at very high dose levels.

Although preruminants such as lambs may be treated orally or parenterally, animals possessing a functional rumen should only be treated parenterally.

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Marketing Authorisation No: Vm 42058/4013

POM-V

To be supplied only on veterinary prescription.

PRODUCT SUMMARY

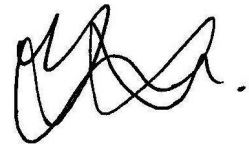
Long-acting – Clinically effective for 48 hours.

Kills Bacteria Rapidly - increases the likelihood of a rapid cure.

Broad Spectrum of Activity - effective in a wide range of conditions.

Excellent Penetration - high levels of CLAMOXYL at the common infection sites give greater chances of success.

High Efficacy - demonstrated in field trials.

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 08 April 2022