PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (100 ML LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl™ Ready-To-Use 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml suspension contains 150 mg amoxicillin as Amoxicillin trihydrate in oily base.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs, cats, sheep, pigs and cattle

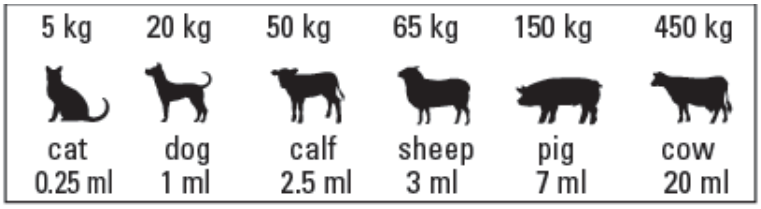
6. INDICATION(S)

See package leaflet for full instructions, contra-indications, warnings, disposal advice etc.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial well before use.

The dosage rate of 7 mg/ is recommended. The following is intended as a guide.



8. WITHDRAWAL PERIOD

Milk (Cattle): 60 hours.

Meat and offal: Cattle: 54 days, Sheep: 47 days, Pigs: 47 days.

Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Penicllins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not broach more than 40 times.

Once the vial has been broached its contents should be used within four weeks.

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 42058/4016

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (250 ML LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl™ Ready-To-Use 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml suspension contains 150 mg amoxicillin as Amoxicillin trihydrate in oily base.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Dogs, cats, sheep, pigs and cattle

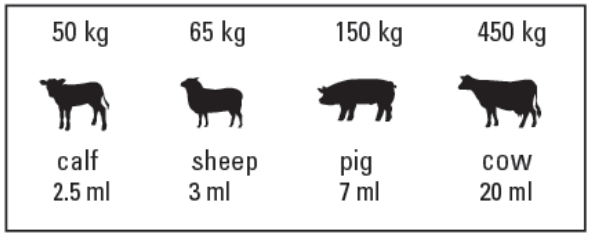
6. INDICATION(S)

See package leaflet for full instructions, contra-indications, warnings, disposal advice etc.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial well before use.

The dosage rate of 7 mg/ is recommended. The following is intended as a guide.



These doses are equivalent to 0.25 ml/5 kg daily.

8. WITHDRAWAL PERIOD

Milk (Cattle): 60 hours.

Meat and offal: Cattle: 54 days, Sheep: 47 days, Pigs: 47 days.

Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Penicllins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not broach more than 40 times.

Once the vial has been broached its contents should be used within four weeks.

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

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:

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KT22 7LP

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4016

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (6 x 100 ML OUTER LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl™ Ready-To-Use 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 150 mg amoxicillin as Amoxicillin Trihydrate in an oily base.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

6 x 100 ml

5. TARGET SPECIES

Dogs, cats, sheep, pigs and cattle

6. INDICATION(S)

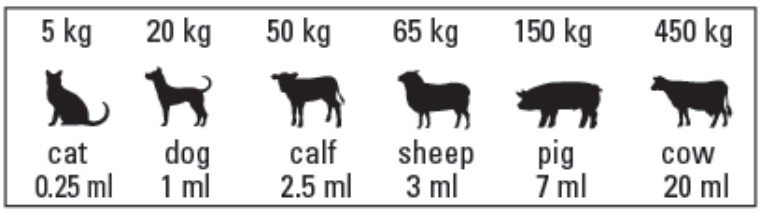
-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial well before use.

The dosage rate of 7 mg/kg which is recommended.

The following is intended as a guide.



These doses are equivalent to 0.25 ml/5 kg daily.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Milk (Cattle): 60 hours.

Meat and offal: Cattle, 54 days, Sheep: 47 days, Pigs: 47 days.

Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Use of the product may occasionally result in local tissue reaction.

User warnings: Penicllins/cephalosporins may occasionally cause severe allergic reactions (see package leaflet for full user warnings).

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not broach more than 40 times.

This product does not contain an antimicrobial preservative. 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:
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1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4016

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (4 x 250 ML OUTER LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl™ Ready-To-Use 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 150 mg amoxicillin as Amoxicillin Trihydrate in an oily base.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

4 x 250 ml

5. TARGET SPECIES

Dogs, cats, sheep, pigs and cattle

6. INDICATION(S)

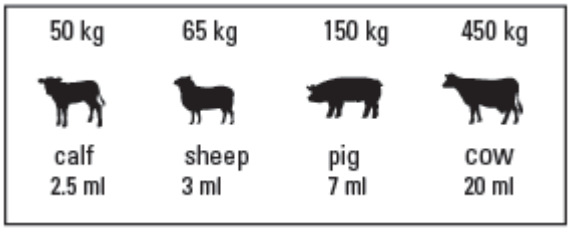
-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial well before use.

The dosage rate of 7 mg/kg which is recommended.

The following is intended as a guide.



These doses are equivalent to 0.25 ml/5 kg daily.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Milk (Cattle): 60 hours.

Meat and offal: Cattle, 54 days, Sheep: 47 days, Pigs: 47 days.

Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Use of the product may occasionally result in local tissue reaction.

User warnings: Penicllins/cephalosporins may occasionally cause severe allergic reactions (see package leaflet for full user warnings).

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not broach more than 40 times.

This product does not contain an antimicrobial preservative. 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 42058/4016

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR:

Clamoxyl™ Ready-To-Use 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 7LP

[Batch release site not currently stated]

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl Ready-To-Use 150 mg/ml suspension for injection

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

Clamoxyl Ready-To-Use 150 mg/ml suspension for injection is an off-white suspension containing 150 mg/ml amoxicillin as Amoxicillin trihydrate.

4. INDICATION(S)

In vitro spectrum.

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:

Actinomyces bovis
Bacillus anthracis
Bordetella bronchiseptica
Clostridium spp.
Corynebacterium spp.
Escherichia coli
Fusobacterium spp.
Haemophilus spp.
Moraxella spp.
Pasteurella spp.
Proteus mirabilis
Salmonella spp.
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 very rapidly. This speed of action is of particular value when animals are at risk or distressed.

For the control of infections caused by amoxicillin susceptible organisms dogs, cats, cattle, pigs and sheep.

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.

5. CONTRAINDICATIONS

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

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.

6. ADVERSE REACTIONS

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

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

Dogs, cats, cattle, pigs and sheep.

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

The recommended dosage rate is 7 mg/kg bodyweight once daily for up to 5 days by subcutaneous (dogs, cats), or intramuscular (dogs, cats, sheep, pigs and cattle) injection.

Animal	Specimen weight kg	Dose of Amoxicillin in mg	Dose volume
Cattle	450	3,000	20.0 ml
Store Cattle	200	1,400	9.0 ml
Calf	50	350	2.5 ml
Sheep	65	450	3.0 ml

Lamb	10	70	0.5 ml
Sow	150	1,050	7.0 ml
Porker	70	490	3.5 ml
Piglet	7	49	0.5 ml
Dog large	35	245	1.5 ml
medium	20	140	1.0 ml
small	10	70	0.5 ml
Cat	5	35	0.25 ml

As a guide this is equivalent to 0.25 ml per 5 kg daily.

9. ADVICE ON CORRECT ADMINISTRATION

If the volume to be given is greater than 15 ml (cattle) and 5 ml (sheep and pigs), the dose should be divided and the remaining should be injected at another site.

Shake the vial well before use.

Swab rubber septum and remove required volume aseptically.

Do not broach more than 40 times.

Massage the injection site after 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 : Cattle: 54 days.
Sheep: 47 days
Pigs: 47 days

Milk: Cattle: 60 hours from the last treatment.

Not to be used in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

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

Do not broach more than 40 times.

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

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.

12. SPECIAL WARNING(S)

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 a 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

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

April 2022

15. OTHER INFORMATION

Clamoxyl Ready-To-Use is available in 100 ml and 250 ml vials. Not all pack sizes may be marketed.

FURTHER INFORMATION

The following features of Clamoxyl Ready-To-Use 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 recrudescense 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 calves and lambs may be treated orally or parenterally, animals possessing a functional rumen should only be treated parenterally.

Clamoxyl Ready-To-Use Injection is not effective against β-lactamase producing organisms.

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

Marketing Authorisation No: Vm 42058/4016

POM-V

To be supplied only on veterinary prescription.

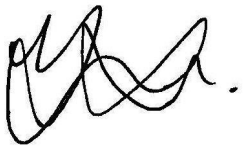
PRODUCT SUMMARY

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

Broad Spectrum of Activity - effective in an extensive and diverse range of conditions.

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

High Efficacy – this has been demonstrated in extensive field trials.



Approved: 08 April 2022