

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl Palatable Tablets 200 mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 200 mg amoxicillin as amoxicillin trihydrate in a highly palatable base.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

250 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

N/A

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For full instructions, warnings and disposal advice, see package leaflet.

Dosage guide:

Dogs (per 20 kg) 1/2 - 1 tablet twice daily.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

In common with all penicillins Clamoxyl should not be given to penicillin sensitive animals.

Do not use on rabbits, guinea-pigs, hamsters or gerbils.

Penicillins/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 reactions 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.

Wash hands after use.

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.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place.

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

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

[Distribution category]

POM-V

For animal treatment only. 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

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

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4014

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR: Clamoxyl Palatable Tablets

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl Palatable Tablets 40 mg and 200 mg

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

Clamoxyl Palatable Tablets are prepared as speckled off-white flat circular tablets with a break line on one face. The tablets contain either 40 mg or 200 mg amoxicillin as amoxicillin trihydrate in a highly palatable base.

4. INDICATION(S)

USES

Clamoxyl is a broad spectrum semi-synthetic penicillin which is bactericidal against a wide range of Gram-negative and Gram-positive bacteria found in dogs and cats including the following:

• *Escherichia coli* • *Salmonella* spp. • *Haemophilus* spp. • Staphylococci (penicillin sensitive strains) • *Leptospira* spp. • Streptococci • *Pasteurella* spp. • *Proteus mirabilis*

When susceptible organisms are present Clamoxyl may be effective in the following indications:

- localised infections - urogenital tract infections
- alimentary tract infections - secondary bacterial infections
- respiratory infections - generalised infections

5. CONTRAINDICATIONS

In common with all other penicillins, Clamoxyl should not be given to penicillin sensitive animals.

Clamoxyl 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

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7. TARGET SPECIES

Cats, Dogs (as logos)

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

The dose rate 4-10 mg/kg twice daily is recommended. In severe or acute conditions, these levels may be increased and/or repeated at more frequent intervals at the clinician's discretion.

The following is intended as a guide:

Cats $\frac{1}{2}$ - 1 x 40 mg tablet twice daily

Dogs per 10 kg 1-2 x 40 mg tablets twice daily or per 20 kg $\frac{1}{2}$ - 1 x 200 mg tablet twice daily

Because of the high blood levels rapidly achieved after oral dosing, parenteral antibiotic treatment has generally been found to be unnecessary even in the presence of systemic diseases. However, where parenteral treatment is required, the tablets are valuable for use as follow-up therapy.

9. ADVICE ON CORRECT ADMINISTRATION

Clamoxyl Palatable Tablets are often accepted from the hand even by sick cats and dogs. Alternatively, the tablets may be crushed and added to a little feed.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a cool dry place.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

OPERATOR WARNINGS

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 reactions 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 with breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

For animal treatment only.

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

August 2020

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

Clamoxyl Palatable Tablets are supplied in:

Securitainers - 40 mg x 500 or 200 mg x 250

Blister packs - 40 mg x 100

Not all pack sizes may be marketed.

FURTHER INFORMATION

The following features of Clamoxyl Palatable Tablets warrant special mention:

1. Oral absorption is particularly good.
2. After absorption amoxicillin is widely distributed throughout the tissues, with especially high levels in the kidneys, urine, liver and bile.
3. In respiratory infection, 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.

Marketing authorisation numbers: 40mg Vm 42058/4015
200mg Vm 42058/4014

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Approved 21 August 2020

A handwritten signature in black ink, consisting of a stylized, cursive initial followed by the name "Hunter." with a period.