SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLAMOXYL Palatable Tablets 40 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The 40 mg tablet has the following composition:

Active ingredients
Amoxicillin as amoxicillin trihydrate - 40 mg/tablet

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet.
Speckled, off-white circular tablets with a break line on one side, for oral dosing.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Amoxicillin is a broad spectrum semi-synthetic penicillin which is bactericidal against a wide range of Gram-positive and Gram-negative bacteria found in dogs and including the following:
Haemophilus spp., *Pasteurella* spp., *Proteus mirabilis*, *Salmonella* spp., Staphylococci (penicillin-sensitive strains), *Leptospira* spp., Streptococci and *Escherichia coli.*
When susceptible organisms are present, the product may be effective in the following indications: localised infections, alimentary tract infections, respiratory infections, urogenital tract infections, secondary bacterial infections and generalised infections.

4.3 Contraindications

In common with all penicillins do not administer to penicillin-sensitive animals.
Not to be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Not to be used in cases of known hypersensitivity.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

4.6 Adverse reactions (frequency and seriousness)

See section 4.10 (Overdose).

4.7 Use during pregnancy, lactation or lay

May be used safely in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use concurrently with bacteriostatic antimicrobials.

4.9 Amounts to be administered and administration route

Dosage Rate:

An oral dose rate of 4 to 10 mg/kg twice daily is recommended (1 to 2 tablets per 10 kg bodyweight twice daily). In severe or acute conditions, these levels may be increased and/or repeated at more frequent intervals.

Dosage Guide:

Cats:	½ - 1 x 40 mg tablet twice daily
Dogs per 10 kg:	1 or 2 x 40 mg tablets, twice daily

The tablets are often accepted from the hand, even by sick animals. Alternatively, the tablets may be crushed and added to a little food.
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 infection. However, where parenteral treatment is required, the tablets may be useful as follow-up therapy.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Amoxicillin is of a low order of toxicity to the target species and is well tolerated by the oral route. Apart from occasional instances of diarrhoea, which have been reported with the recommended dose, no adverse side effects are to be expected from accidental overdose.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Bactericidal against a wide range of Gram-negative and Gram-positive bacterial pathogens found in dogs and cats including the following:
Haemophilus spp.
Pasteurella spp.
Proteus mirabilis
Salmonella spp.
Staphylococci (penicillin-sensitive strains)
Leptospira spp.
Streptococci
Escherichia coli.

The following features are important:
1. Oral absorption is particularly good.
2. After absorption amoxicillin is widely distributed throughout the tissue with especially high levels in the kidney, urine, liver and bile.
3. Amoxicillin shares with other penicillins the virtual absence of toxicity problems even at very high dose levels.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Silica Colloidal Anhydrous
Yeast
Methyl Cellulose
Microcrystalline Cellulose

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Store in a dry place.
Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

Aluminium foil blister packs containing 100 x 40 mg tablets.
Polypropylene securitainers containing 500 x 40 mg tablets.
Aluminium canister with screw-fit cap containing 500 x 40 mg tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

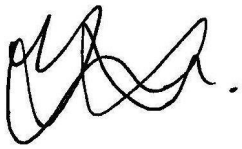
Vm: 42058/4015

9. DATE OF THE FIRST AUTHORISATION

19 February 1990

10. DATE OF REVISION OF THE TEXT

September 2020



Approved: 02 September 2020