PARTICULARS TO APPEAR ON THE OUTER PACKAGE cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 400 mg/100 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	400 mg
Clavulanic acid (as potassium clavulanate)	100 mg

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
50 tablets
80 tablets
100 tablets
250 tablets
500 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Any divided tablet portion remaining after 24 hours should be discarded.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store in a dry place.
Divided tablets should be stored in the blister pack.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VMD NV

14. MARKETING AUTHORISATION NUMBERS

Vm 19968/4004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 400 mg/100 mg tablets for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin	400 mg/Tablet
Clavulanic acid	100 mg/Tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clavucill 400 mg/100 mg tablets for dogs

2. Composition

Each tablet contains:

Active substances:
Amoxicillin 400 mg (equivalent to 459.1 amoxicillin trihydrate)
Clavulanic acid 100 mg (equivalent to 119.14 potassium clavulanate)
Excipient: Erythrosine (E127) 0.50 mg

Pale pink, rounded, one side scored, uncoated tablet with a diameter of 18.3 mm.
The tablets can be divided into two equal parts.

3. Target species

Dogs

4. Indications for use

For the treatment of
- Skin infections (including deep and superficial pyoderma).
- Soft tissue infections (including anal sacculitis and abscesses).
- Urinary tract infections.
- Respiratory infections.
- Intestinal infections.
- Periodontal infections (infections of the tissues surrounding the teeth) in addition to mechanical or surgical periodontal therapy.

5. Contraindications

Do not use in rabbits, guinea pigs, hamsters, gerbils, chinchillas or other small herbivores.

Do not use in cases of hypersensitivity to the active substances, other substances of the beta-lactam group or to any of the excipients.

Do not administer to horses or ruminating animals.

Do not use in animals with severe renal impairment with no or decreased urine production (anuria or oliguria).

6. Special warnings

Special warnings:
Cross-resistance has been shown between amoxicillin/clavulanic acid and other antibiotics belonging to the beta-lactam group. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to other antimicrobials in the beta-lactam group because its effectiveness may be reduced.

When susceptibility testing has shown resistance to sole beta-lactam, but susceptibility to combination of amoxicillin/clavulanic acid has been confirmed, treatment with the veterinary medicinal product might nevertheless be considered.

Do not use in cases of suspected or confirmed methicillin resistant *S. aureus* (MRSA) and methicillin resistant *S. pseudintermedius* (MRSP) infections, as such isolates should be considered resistant to all beta-lactams including amoxicillin/clavulanic acid combinations.

The veterinary medicinal product has no effect against infections caused by *Pseudomonas* spp. due to its inherent resistance.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Pharmacokinetic of the active substances in the target tissue might be considered as well.

The routine use of systemic antibiotics for intestinal infections is not recommended.

Oral treatment with antibiotics can result in disturbance of gastrointestinal flora, especially in case of long-term treatment.

In case of renal or hepatic insufficiency, the use of the veterinary medicinal product should be subject to a benefit-risk assessment by the responsible veterinarian.

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 can lead to cross-reactions with cephalosporins and vice versa. Allergic reactions caused by these substances may occasionally be serious.

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product. Wear gloves when handling this product to avoid skin contact.

If you develop symptoms such as a skin rash and persistent eye irritation after exposure to the veterinary medicinal product, seek medical advice immediately and show the package leaflet or label to the physician. Swelling of the face, lips, or eyes, or difficulty breathing are more serious symptoms that require urgent medical attention.

Wash hands after use.

To prevent children from accessing the veterinary medicinal product, only the required number of tablets should be removed from the blister pack and only when required. Store any unused portion of the tablet in the opened blister pack and return it into the carton immediately after use. The carton should be stored out of the sight and reach of children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

In laboratory studies (rat, mouse), signs of embryotoxicity or teratogenicity could only be detected at high doses.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The bactericidal effect of amoxicillin may be inhibited by the concomitant use of bacteriostatic antimicrobials.

Penicillins may increase the effect of aminoglycosides.

Overdose:
Doses up to 40 mg amoxicillin and 10 mg clavulanic acid/kg administered twice daily for 5 days were tolerated well in young dogs.

No adverse events associated with overdoses other than those listed in section ‘Adverse events’ were detected in the respective studies (for information on symptomatic treatment see also section on adverse events).

Due to the toxic effect of penicillins on the nervous system, overdosing might result in central nervous system symptoms and convulsions. In these cases, treatment with

the veterinary medicinal product should be discontinued immediately and symptomatic treatment should be initiated.

7. Adverse events

Dogs

Common (1 to 10 animals / 100 animals treated):	gastrointestinal disorder[1] (e.g. vomiting, diarrhoea)
Uncommon (1 to 10 animals / 1 000 animals treated):	hypersalivation anorexia[1], lethargy
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	hypersensitivity reaction[2] (e.g. allergic skin reaction, anaphylaxis)

[1] Depending on the severity of the adverse event treatment should be discontinued and symptomatic treatment initiated based on the benefit-risk assessment by the responsible veterinarian.
[2] May be serious. Immediate discontinuation of the veterinary medicinal product is required. Countermeasures to be taken in case of an allergic reaction:
- anaphylaxis: administer epinephrine (adrenaline) and glucocorticoids.
- allergic skin reactions: administer antihistamines and/or glucocorticoids.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

Dosage: 10 mg amoxicillin and 2.5 mg clavulanic acid/kg body weight every 12 hours.
In refractory respiratory tract infections, the dose can be doubled to 20 mg amoxicillin and 5 mg clavulanic acid/kg body weight every 12 hours and the treatment can be prolonged for up to 10 days.

Dosing instructions:

Body weight (kg)	**Number of tablets every 12 hours (10 mg amoxicillin and 2.5 mg clavulanic acid/kg body weight)**
> 10 – 20	0.5
> 20 – 40	1
> 40 – 60	1.5
> 60 – 80	2

Duration of treatment:
In most of the cases, a treatment duration of 5 to 7 days is sufficient.
For chronic cases, a longer course of therapy may be required.
Based on clinical trials, the following treatment durations are recommended:
Chronic skin infections, 10–20 days.
Chronic cystitis, 10–28 days.

9. Advice on correct administration

- To ensure a correct dosage, body weight should be determined as accurately as possible.
- The tablets can be administered directly into the mouth of the animals or crumbled and added to a small quantity of food and fed immediately.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Store in a dry place.
Divided tablets should be stored in the blister pack.
Any divided tablet portion remaining after 24 hours should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and the carton, after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 19968/4004

Pack sizes:
Tablet strips, packed in carton boxes of 10, 20, 30, 50, 80, 100, 250 and 500 tablets.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
VMD NV
Hoge Mauw 900
2370 Arendonk
Belgium

Local representatives and contact details to report suspected adverse reactions:
V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk
Belgium

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 21 October 2026