SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 200 mg/50 mg, Tablets for Dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active ingredients:

Amoxicillin (as amoxicillin trihydrate)	200.0 mg
Clavulanic acid (as potassium clavulanate)	50.0 mg

Excipient(s):

Contains Erythrosine E127	0.25 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet:
Pale pink, bi-convex divisible tablet, scored on one face.
The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Clinically, amoxicillin has been shown to be effective in treating a wide range of diseases of dogs including: skin disease (including deep and superficial pyodermas); soft tissue infections (abscesses and anal sacculitis); dental infections (e.g. gingivitis); urinary tract infection; respiratory disease (involving upper and lower respiratory tract); enteritis.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substances..
This product should not be given rabbits, guinea pigs, hamsters or gerbils. Caution is advised in their 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

This product is not indicated for cases involving *Pseudomonas spp.*
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to penicillins and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials due to the potential for cross-resistance

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 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 with breathing are more serious symptoms and
may require urgent medical attention.
In the event of accidental ingestion seek medical advice. Wash hands after handling the tablets.

4.6 Adverse reactions (frequency and seriousness)

Very occasionally, hypersensitivity reactions to penicillins may occur in treated animals.
Use of the product may result in rare instances of gastro-intestinal disorders (vomiting,
diarrhoea, anorexia).

4.7 Use during pregnancy, lactation or lay

Can be safely used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure a correct dosage, bodyweight should be determined as accurately as possible.
Dose rate: 12.5 mg/kg bodyweight twice daily.
For oral administration only. The tablets should be administered directly into the mouth.
Dose: The following table is intended as a guide to dispensing at the standard dose rate of 12.5 mg/kg, twice daily.

Bodyweight (kg)	**Number of tablets per dose twice daily**	
	50mg	**250mg**
1 –2	½	-
3 – 5	1	-
6 – 9	2	-
10 – 13	3	-
14 – 18	4	-
19 – 25	-	1
26 - 35	-	1½
36 – 49	-	2
50 – 60	-	3

The products are effective against Klebsiella infections found in veterinary practice, but are not indicated for cases involving *Pseudomonas* species.
The majority of routine cases respond to between 5 and 7 days therapy. In chronic or refractory cases, a longer course of therapy may be required e.g. chronic skin disease 10 – 20 days, chronic cystitis 10 – 28 days, respiratory disease 8 – 10 days.
Refractory cases however particularly of the respiratory tract, have shown improved cure rates by doubling the dose to 25 mg/kg bodyweight twice daily.

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

The product is of low order toxicity to the target species. No adverse side effects are to be expected from accidental overdose.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group. Beta-lactam antibacterials; amoxicillin and enzyme inhibitor.
ATCvet code: QJ01CR02

5.1 Pharmacodynamic properties

The tablets have a notably broad spectrum of bactericidal activity against bacteria commonly found in dogs. Resistance to many antibiotics is caused by ß-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate counteracts this defence mechanism by inactivating the ß-lactamases, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the body.
In vitro the product is active against a wide range of clinically important aerobic and anaerobic bacteria, including:
Gram-positive: Staphylococci (including β-lactamase-producing strains) *Clostridia*; *Corynebacteria*; *Peptostreptococcus* spp.; *Streptococci*.

Gram-negative: *Bacteroides* spp. (including β-lactamase-producing strains); *Escherichia coli* (including most β-lactamase producing strains); *Salmonellae* (including β-lactamase-producing strains); *Bordetella bronchiseptia*; *Campylobacter* spp.; *Fusobacterium necrophorum*; *Klebsiellae*; *Pasteurellae*; *Proteus* spp.

5.2 Pharmacokinetic particulars

Following the administration of Clavucill in dogs, a mean Cmax of 4.22 μg/ml and 12.5μg/ml was achieved at approximately 0.97 hours and 1.18 hours for Clavulanic acid and Amoxycillin respectively. The mean half-life was 0.63 hours and 1.57 hours for clavulanic acid and amoxicillin respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Erythrosine E127
Colloidal anhydrous silica
Sodium starch glycolate Type A
Microcrystalline Cellulose
Magnesium Stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 24 hours

6.4 Special precautions for storage

Do not store above 25 °C.
Store in a dry place.
Return any halved tablet to the opened strip-pack and use within 24 hours.

6.5 Nature and composition of immediate packaging

The tablets are packed in heat sealed polyester/aluminium/polyethylene foil strips, with 10 tablets per strip.

Detailed composition:
- Polyester: 12 µm
- Laminating agent: 3 g/m^2
- Aluminium foil: 20 µm
- Laminating agent: 3 g/m^2
- LD Polyethylene: 30 µm

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

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

V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 19968/4002

9. DATE OF FIRST AUTHORISATION

29 August 2008

10. DATE OF REVISION OF THE TEXT

June 2015

APPROVED T. NASH **10/06/15**