SUMMARY OF PRODUCT CHARACTERSITICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 400 mg/100 mg, Tablets for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	mg per tablet
Active ingredients:	
Amoxicillin as amoxicillin trihydrate	400.0
Clavulanic acid (as potassium clavulanate)	100.0
Excipient(s):	
Contains Erythrosine E127.	0.50

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet:
Pale pink, bi-convex divisible tablet, scored on one face.

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 pyoderma); urinary tract infection; respiratory disease involving upper and lower respiratory tract; enteritis; dental infections (e.g. gingivitis); soft tissue infections (e.g. abscesses and anal sacculitis).

Note: The product is not indicated for cases involving *Pseudomonas* spp.

4.2 Contraindications

Do not use in animals known to be hypersensitive to penicillins.
Do not use in rabbits, guinea pigs 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

None

ii) Special precautions to be taken by the person administering the veterinarymedicinal 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 occasional 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)

None known

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy
Can be used during lactation

4.8 Interaction with other medicinal products and other forms of interaction

Should not be administered concomitantly with bacteriostatic antibiotics, which are incompatable.

4.9 Amounts to be administered and administration route

Administration: For oral administration only.
Dosage rate: Dogs: 12.5 mg/kg bodyweight, twice daily.
Dosage guide: The tablets may be crushed and added to a small quantity of food.

The majority of routine cases will respond to between 5 and 7 days therapy. Because of the low toxicity profile, the dose can be doubled if desired in refractory cases.
In certain indications, for example canine pyoderma and chronic cystitis, bacterial infection may be secondary to other pathology. For such cases long

courses of antibacterial therapy may be required, in addition to diagnosis and treatment of the underlying condition. In such circumstances overall treatment length must be at the clinician's discretion, but should be long enough to ensure complete resolution of the bacterial disease.

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

Amoxicillin is of a low order of toxicity and is well tolerated by the oral route in the dogs. Limited overdose normally produces no adverse effect. If signs do occur, for example of gastro-intestinal disturbance treatment should be symptomatic.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL IMMUNOLOGICAL PROPERTIES

ATCvet code: QJ01CR02
The ingredients have a notably broad spectrum of bactericidal activity against bacteria commonly found in dogs.

5.1 Pharmacodynamic properties

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*; *Actinomyces*; *Peptostreptococcus* spp.; *Streptococci*; *Enterococci*

Gram-negative: *Bacteroides* spp. (including β-lactamase-producing strains); *Escherichia coli* (including 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
Colloidal anhydrous silica
Sodium starch glycolate
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.
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 2 tablets per strip.

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 11990/4049

9. DATE OF FIRST AUTHORISATION

29 August 2008

10. DATE OF REVISION OF THE TEXT

June 2015

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