<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 400 mg/100 mg, Tablets for dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 mg Clavulanic acid as Potassium clavulanate and 400 mg amoxicillin as Amoxicillin trihydrate.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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).
The product is effective against Klebsiella infections found in veterinary practice, but it is not indicated for cases involving Pseudomonas species.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration
Dosage Guide: Dose rate 12.5 mg/kg bodyweight twice daily.

Bodyweight (kg)	Number of tablets per dose twice daily		
	50mg	250mg	500mg
1 –2	½	-	-
3 – 5	1	-	-
6 – 9	2	-	-
10 – 13	3	-	-
14 – 18	4	-	-
19 – 25	-	1	-
26 - 35	-	1½	-
36 – 49	-	2	1
50 – 60	-	3	1½
61 - 80	-	-	2

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reaction 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 may require urgent medical attention.

In the event of accidental ingestion seek medical advice. Wash hands after handling the tablets.

Do not use in animals known to be hypersensitive to penicillins.
Should not be given to rabbits, guinea pigs, hamsters or gerbils.
Caution is advised in their use in any other very small herbivores.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

N/A

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

For further information contact: **V.M.D. n.v.**

16. MARKETING AUTHORISATION NUMBER(S)

Vm 19968/4004

17. MANUFACTURER'S BATCH NUMBER

BN{number}

POM-V
Prescription Only Medicine-Veterinarian
To be supplied only on veterinary prescription

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 400 mg/100 mg, tablets for dogs.
Amoxicillin + clavulanic acid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

V.M.D.n.v.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
Clavucill 400 mg/100 mg, Tablets for dogs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 400 mg/100 mg, Tablets for dogs.

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

The composition of the tablets are as follows:
500mg – 400mg amoxicillin
100mg clavulanic acid

Clavucill 400 mg/100 mg is presented as pale pink, rounded, one side scored, uncoated tablet. Each tablet contains clavulanic acid as potassium clavulanate and amoxicillin as Amoxicillin trihydrate.

4. INDICATION(S)

500 mg: Dogs

Clinically Clavucill has been shown to be effective in treating a wide range of diseases in dogs including:

- Skin disease (including deep and superficial pyodermas)
- Soft tissue infections (abscesses and anal sacculitis)
- Dental infections (e.g. gingivitis)
- Urinary tract infections
- Respiratory diseases (involving upper and lower respiratory tract)
- Enteritis

5. PRODUCT SUMMARY

Extended Spectrum of Activity – clavulanate extends the spectrum of amoxicillin by making it active against

resistant (ß-lactamase producing) strains of Staphylococci, E.Coli, Bacteroides and Salmonellae, as well as
adding Klebsiella species to the list of susceptible organisms.
- Kills Bacteria Rapidly – increases the likelihood of a rapid clinical cure.
- Excellent Absorption and Penetration – ensures sufficiently high levels of the product at the common
infection sites to achieve clinical success.
- Easy to Administer – exceptional palatability makes the tablets readily acceptable to dogs and cats.
- Simple Twice Daily Dosage – easy to remember.
- Convenient Foil Packaging – easy to dispense.

6. CONTRAINDICATIONS

Do not use in animals known to be hypersensitive to penicillins.
Do not use in rabbits, guinea pigs, hamsters or gerbils.
Caution is advised in their use in any other very small herbivores.
For animal treatment only.

7. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this package leaflet please inform your veterinary surgeon.

8. TARGET SPECIES

500 mg: Dogs

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

For oral administration only. The tablets may be crushed and added to a little food.

Dose: The following table is intended as a guide to dispensing Clavucill 400 mg/100 mg at the standard dose rate of 12.5 mg/kg, twice daily.

Bodyweight (kg)	**Number of tablets per dose twice daily**		
	50mg	**250mg**	**500mg**
1 –2	½	-	-
3 – 5	1	-	-
6 – 9	2	-	-
10 – 13	3	-	-
14 – 18	4	-	-
19 – 25	-	1	-
26 - 35	-	1½	-
36 – 49	-	2	1
50 – 60	-	3	1½
61 - 80	-	-	2

For the majority of infections, including those of the skin, urinary tract and gastrointestinal tract, the above dosing regime is effective.
Refractory cases, however particularly those of the respiratory tract, have shown improved cure rates by doubling the dose to 25 mg/kg bodyweight twice daily. (Note that animals of 1 kg bodyweight when dosed with ½ tablet will already be receiving the double dose rate).

Duration of therapy:
Routine cases involving all indications:
The majority of these cases respond to between 5 and 7 days therapy.

Chronic or 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.

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 these cases, where there is considerable tissue damage, a longer course of therapy may be required in that it allows sufficient time for damaged tissue to repair.
Based on clinical trials, the following durations are suggested as guidelines:
Chronic skin disease ..... 10 – 20 days
Chronic cystitis ..... 10 – 28 days
Respiratory disease..... 8 – 10 days

10. ADVICE ON CORRECT ADMINISTRATION

N/A

11. WITHDRAWAL PERIOD

N/A

12. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep out of the sight and reach of children.
Keep blister in outer carton.
Return any halved tablet to the opened strip pack and use within 24 hours.

13. SPECIAL WARNING(S)

Use during pregnancy, lactation or lay
Can be safely used in pregnant or lactating animals.

Special warnings
For animal treatment only.

User 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 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.

Overdose
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of used packaging in the household refuse. Unused tablets should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

xx

15. OTHER INFORMATION

For further information contact V.M.D.n.v.
Manufacturer:
V.M.D. n.v.
Hoge Mauw 900
2370 Arendonk
Belgium

POM-V

Prescription Only Medicine -Veterinarian
To be supplied only on veterinary prescription.

500 mg – Vm 19968/4004

Approved: 27 December 2018