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

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavucill 200 mg/50 mg, tablets for dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 50 mg Clavulanic acid as Potassium clavulanate and 200 mg amoxicillin as Amoxicillin trihydrate.
0.25 mg Erythrosine E127
The tablets can be divided into equal halves.

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 products are effective against Klebsiella infections found in veterinary practice, but are 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
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

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.

The product should not be given to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in their use in any other very small herbivores.
This product is not indicated for cases involving *Pseudomonas* spp.
Do not use in animals with known hypersensitivity to the active substances.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Keep blister in outer carton.
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

Read the package leaflet before use.

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 SIGHT AND REACH 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)

VPA 10817/002/002
Vm 19968/4002

17. MANUFACTURER'S BATCH NUMBER

BN{number}
IE:

POM

Prescription Only Medicine

UK:

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 200 mg/50 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 40 mg/10 mg, tablets for dogs and cats.
Clavucill 200 mg/50 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 40 mg/10 mg, tablets for dogs and cats.
Clavucill 200 mg/50 mg, tablets for dogs.

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

The composition of the tablets are as follows:

50mg - 40mg amoxicillin
10mg clavulanic acid
0.05 mg Erythrosine E127

250mg - 200mg amoxicillin
50mg clavulanic acid
0.25 mg Erythrosine E127

The products are 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)

the products have been shown to be effective in treating a wide range of diseases of cats (Clavucill 40 mg/10 mg) and dogs (Clavucill 40 mg/10 mg and Clavucill 200 mg/50 mg) 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. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active substances.
This product should not be given to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in their use in any other small herbivores. For animal treatment only.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Clavucill 40 mg/10 mg: Cats & Dogs
Clavucill 200 mg/50 mg: Dogs

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

To ensure a correct dose, bodyweight should be determined as accurately as possible.
For oral administration only.
Dose: The following table is intended as a guide to dispensing the product 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 particularly of the respiratory tract, have shown improved cure rates by doubling the dose to 25 mg/kg bodyweight twice daily.

9. ADVICE ON CORRECT ADMINISTRATION

The tablets should be administered directly into the mouth.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Store in a dry place.
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.
Do not use these veterinary medicinal products after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last date of that month.

12. SPECIAL WARNING(S)

Special warnings
For Animal Treatment Only.
Can be safely used in pregnant or lactating 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
Resistance to many antibiotics is caused by β-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate counteracts this defence mechanism by inactivating the β-lactamases, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the body.
The product is effective against Klebsiella infections found in veterinary practice, but is not indicated for cases involving *Pseudomonas* species

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 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.

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

XX

15. OTHER INFORMATION

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

Not all pack sizes maybe marketed

PRODUCT SUMMARY

Pharmacodynamic properties
Resistance to many antibiotics is caused by β-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanate in Clavucill counteracts this defence mechanism by inactivating the β-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.

IRELAND ONLY
50 mg - VPA 10817/002/001
250 mg - VPA 10817/002/002
POM
Prescription Only Medicine

UNITED KINGDOM ONLY
Clavucill 200 mg/50 mg tablets for dogs: Vm 19968/4002
Clavucill 40 mg/ 10 mg tablets for dogs and cats: Vm 19968/4003

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

Approved: 27 December 2018