PACKAGE LEAFLET

Clavucill 200 mg/50 mg (DE, DK, ES, FR, NL, PL, PT, RO, SE, BE), tablets for dogs.
Amoxicillin + clavulanic acid

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 200 mg/50 mg (DE, DK, ES, FR, NL, PL, PT, RO, SE, BE), tablets for dogs

Amoxicillin + clavulanic acid

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

- Active substances: Amoxicillin (as amoxicillin trihydrate) 200 mg/tablet
  Clavulanic acid (as potassium clavulanate) 50 mg/tablet
- Excipients: Erythrosine (E127) 0.25 mg

4. INDICATIONS

Dogs
Treatment of infections caused by micro-organisms sensitive for the combination amoxicillin/clavulanic acid, especially:
- dermatitis (superficial and deep pyodermatitis) caused by *Staphylococcus intermedius*.
- urinary tract infections caused by *E. coli*.
- respiratory tract infections caused by *Streptococcus* spp.
- enteritis caused by *E. coli*.

5. CONTRAINDICATIONS

- Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group.
- Do not use in case of serious dysfunction of the kidneys accompanied by anuria and oliguria.
- Do not use in rabbits, guinea pigs, hamsters, chinchillas or gerbils.

6. ADVERSE REACTIONS

- Dose independent allergic reactions may occur, such as skin reactions or anaphylaxis. In those cases the treatment must be stopped immediately and a symptomatic treatment should

be given.

- Gastro-intestinal disturbances (diarrhoea, vomiting, …) may occur after administration of the product.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Oral use.
Amounts to be administered: The recommended dose rate is 10 mg amoxicillin / 2.5 mg clavulanic acid per kg bodyweight (= 12.5 mg of combined active substances) twice a day by the oral route in dogs, i.e. 1 tablet per 20 kg body weight every 12h.

Body weight (kg)	**Number of tablets (twice daily)**
< 8	Use 50 mg
(8.1 – 10.0)	½
(10.1 – 20.0)	1
(20.1 – 30.0)	1 ½
(30.1 – 40.0)	2
> 40	Use 500 mg tablets

In case of complicated infections, especially respiratory infections, a better cure rate is obtained with a double dose, up to 25 mg of the combination of the active substances per kg weight, twice daily.

Treatment duration:
In the majority of cases, a treatment of 5 to 7 days is sufficient.
For chronic and refractory infections, longer courses of antibacterial therapy may be required. Treatment length should be adapted by the veterinarian, and should be long enough to ensure complete bacteriological cure.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

9. ADVICE ON CORRECT ADMINISTRATION

- Do not use in case of known resistance to the combination.
- Official, national and regional antimicrobial policies with respect to the use of broad-spectrum antibiotics should be taken into account.
- Do not use in case of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as single substance.

- It is advised that upon initiating therapy appropriate sensitivity testing is performed and that therapy is continued only after susceptibility to the combination has been established.
- Use of the product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to the amoxicillin/clavulanate, and may decrease the effectiveness of treatment with β-lactam antibiotics
- In animals with hepatic and renal failure, the dosing regimen should be carefully evaluated.
- Caution is advised in the use in small herbivores other than those in the section 5.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep out of the reach and sight of children.
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Divided tablets should be stored in the blister pack. Any divided tablet portion remaining after 24 hours should be discarded.
Do not use after the expiry date stated on the blister and the carton.

12. SPECIAL WARNINGS

Penicillins and cephalosporins may cause hypersensitivity reactions (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa.
Allergic reactions to these substances may occasionally be serious.
- People with known hypersensitivity to penicillins should avoid contact with the veterinary medicinal product.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
- Wash hands after use.

- **Use during pregnancy or lactation:** Laboratory studies in rats and mice have not produced any evidence of teratogenic or foetotoxic effects. No studies have been conducted in pregnant or lactating dogs. Use only according to the benefit/risk assessment by the responsible veterinarian.
- **Interactions:** Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effects of penicillins.
The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.
- **Overdose:** Mild gastrointestinal symptoms (diarrhea, vomiting) may occur more frequently after overdose of the product.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Delivery: veterinary prescription only.
Not all pack sizes may be marketed.
Pack sizes: 10, 100 or 250 tablets