

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavoral 500/125 mg tablets for dogs
Amoxicillin/Clavulanic acid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Amoxicillin (as amoxicillin trihydrate) 500 mg
Clavulanic acid (as potassium clavulanate) 125 mg

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

10 tablets
20 tablets
100 tablets
10 tablets
100 tablets
250 tablets

5. TARGET SPECIES

Dog.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original package.
Quarter tablets should be returned to the opened strip and stored in a refrigerator.
Quarter tablets should be used within 12 hours.

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

Disposal: read package leaflet

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

For animal treatment only - to be supplied only on veterinary prescription.

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

AST Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

To be established nationally.

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

(Aluminium/aluminium strip)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavoral 500/125 mg tablets for dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

AST Beheer B.V.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

LOT

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Clavoral 500/125 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

Marketing authorisation holder:

AST Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for the batch release:

Lelypharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavoral 500/125 mg tablets for dogs

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

Active substances per tablet:

Amoxicillin (as amoxicillin trihydrate)	500 mg
Clavulanic acid (as potassium clavulanate)	125 mg

Other ingredients

Quinoline yellow lacquer (E104)	0.6 mg
Titanium dioxide (E171)	1.0 mg

Yellowish-white to light yellow round tablet with a cross-shaped break mark on one side.
The tablets can be divided into 4 equal parts.

4. INDICATION(S)

Treatment of infections in dogs caused by bacteria sensitive to amoxicillin in combination with clavulanic acid, particularly:

- Skin infections (including superficial and deep pyodermas) associated with Staphylococci (including beta-lactamase producing strains) and Streptococci.
- Urinary tract infections associated with Staphylococci (including beta-lactamase producing strains), Streptococci, *Escherichia coli* (including beta-lactamase producing strains), *Fusobacterium necrophorum* and *Proteus spp.*
- Respiratory tract infections associated with Staphylococci (including beta-lactamase producing strains), Streptococci and Pasteurellae.
- Gastrointestinal infections associated with *Escherichia coli* (including beta-lactamase producing strains) and *Proteus spp.*
- Infections of the oral cavity (mucous membrane) associated with Clostridia, Corynebacteria, Staphylococci (including beta-lactamase producing strains), Streptococci, *Bacteroides spp* (including beta-lactamase producing strains), *Fusobacterium necrophorum* and Pasteurellae.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group or any of the excipients.

Do not use in serious dysfunction of the kidneys accompanied by anuria and oliguria.

Do not use in rabbits, guinea pigs, hamsters, chinchillas and gerbils.

Do not use in case of known resistance to the combination.

6. ADVERSE REACTIONS

Mild gastrointestinal symptoms (diarrhea, nausea and vomiting) may occur after administration of the product. Allergic reactions (skin reactions, anaphylaxia) may occasionally occur. In these cases, administration should be discontinued and a symptomatic treatment given.

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, ROUTE(S) AND METHOD OF ADMINISTRATION















Posology


For oral administration only.

Dosage

The recommended dose is 12.5 mg of combined active substance (=10 mg amoxicillin and 2.5 mg clavulanic acid) per kg bodyweight twice daily.

The following table is intended as a guide to dispensing the product at the standard dose rate of 12.5 mg of combined actives per kg bodyweight twice daily.

	Number of tablets twice daily		
Bodyweight (kg)	amoxicilline 50 mg/ clavulanic acid 12.5 mg	amoxicilline 250 mg/ clavulanic acid 62.5 mg	amoxicilline 500 mg/ clavulanic acid 125 mg
1 – 1.25			
1.25 – 2.5			
2.5 – 3.75			
3.75 – 5			
5 – 6.25			
6.25 - 12.5			
12.5 - 18.75			
18.75 - 25			
25 - 31.25			
31.25 - 37.5			
37.5 - 50			

50 – 62.5			
62.5 - 75			

In refractory cases of skin infections, a double dose is recommended (25 mg per kg bodyweight, twice daily).

Duration of therapy

The majority of routine cases respond to 5 – 7 days of therapy.

In chronic cases, a longer course of therapy is recommended. 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in the original package.

Keep out of the sight and reach of children.

Quarter tablets should be returned to the opened strip and stored in a refrigerator.

Shelf-life of tablet quarters: 24 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.

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 the SPC may increase the prevalence of bacteria resistant to the amoxicillin/clavulanate, and may decrease the effectiveness of treatment with β -lactam antibiotics due to the potential for cross-resistance.

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.

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 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 require urgent medical attention.

Wash hands after use

Use during pregnancy and lactation

Laboratory studies in rats and mice have not produced any evidence of teratogenic or fetotoxic effects. No studies have been conducted in the pregnant and lactating dogs. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

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 signs (diarrhea, nausea and vomiting) may occur more frequently after overdose of the product.

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

Pack sizes

Carton containing 5 aluminium/aluminium blister strips each strip with 2 tablets corresponding to 10 tablets per carton.

Carton containing 5 aluminium/aluminium blister strips each strip with 4 tablets corresponding to 20 tablets per carton.

Carton containing 25 aluminium/aluminium blister strips each strip with 4 tablets corresponding to 100 tablets per carton.

Carton containing 1 aluminium/aluminium blister strip with 10 tablets corresponding to 10 tablets per carton.

Carton containing 10 aluminium/aluminium blister strips each strip with 10 tablets corresponding to 100 tablets per carton.

Carton containing 25 aluminium/aluminium blister strips each strip with 10 tablets corresponding to 250 tablets per carton.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.