1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYLANIC 500 mg + 125 mg tablets for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

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

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
White to slightly yellow, round and convex tablet with a cross-shaped break line on one side.
The tablets can be divided into 2 or 4 equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For treatment of infections caused by bacteria susceptible to amoxicillin and clavulanic acid including: skin disease (including deep and superficial pyodermas); soft tissue infections (abscesses and anal sacculitis); dental infections (e.g. gingivitis); urinary tract infections; respiratory disease (involving upper and lower respiratory tract); enteritis.

4.3 Contraindications

Do not use in rabbits, guinea pigs, hamsters, gerbils or chinchillas.
Do not use in known cases of hypersensitivity to the active substances, to other antimicrobials of the β-lactam group or to any of the excipients.
Do not use in animals with serious dysfunction of the kidneys accompanied by anuria and oliguria.
Do not use in ruminants and horses.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Official, national and regional antimicrobial policies should be taken into account when the product is used.

The association amoxicillin/clavulanic acid should be reserved for the treatment of clinical conditions which have responded poorly to other classes of antimicrobials or narrow spectrum penicillins. Whenever possible, the association amoxicillin/clavulanic acid should only be used based on susceptibility testing.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin/clavulanic acid and may decrease the effectiveness of treatment with β-lactam antibiotics due to the potential for cross-resistance.
Caution is advised when using the product in small herbivores, other than those which have been contraindicated in section 4.3.
In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- Penicillins 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 require urgent medical attention.
- Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions (skin reactions, anaphylaxis) may occasionally occur. In these cases, administration should be discontinued and a symptomatic treatment given.
Use of the product may result in very rare instances of gastro-intestinal disorders (vomiting, diarrhoea, anorexia).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action. Consider potential cross allergies with other penicillins. Penicillins can increase the effect of aminoglycosides.

4.9 Amounts to be administered and administration route

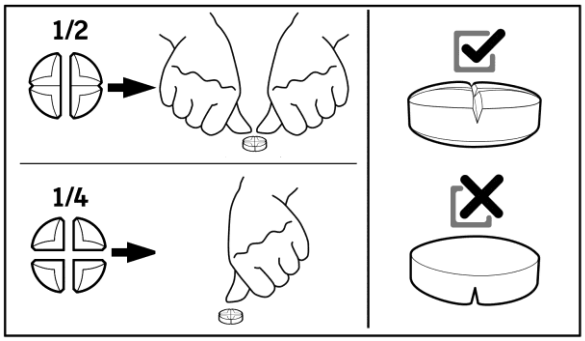
For oral administration.

The recommended dose is 12.5 mg/kg body weight (10 mg amoxicillin/2.5 mg clavulanic acid per kg body weight), twice daily.
The following table is intended as a guide to dispensing the tablets at the recommended dose.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

	Number of tablets twice daily (dosage rate: 12.5 mg/kg b.w.)		
Body weight (kg)	Amoxicillin/clavulanic acid 50 mg + 12.5 mg	Amoxicillin/clavulanic acid 250 mg + 62.5 mg	Amoxicillin/clavulanic acid 500 mg + 125 mg
1-1.25	¼	-	-
>1.25-2.5	½	-	-
>2.5-3.75	¾	-	-
>3.75-5	1	-	-
>5-6.25	1¼	¼	-
>6.25-12.5	-	½	¼
>12.5-18.75	-	¾	-
>18.75-25	-	1	½
>25-31.25	-	1¼	-
>31.25-37.5	-	1½	-
>37.5-50	-	-	1
>50-62.5	-	-	1¼
>62.5-75	-	-	1½

 = ¼ tablet = ½ tablet = ¾ tablet = 1 tablet

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosage.



The minimum treatment duration is 5 days with the majority of routine cases responding after 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.
In such circumstances overall treatment length is 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

Mild gastrointestinal symptoms (diarrhoea and vomiting) may occur more frequently after overdose of the product.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use. Combinations of penicillins, including beta-lactamase inhibitors.
ATCvet code: QJ01CR02.

5.1 Pharmacodynamic properties

Amoxicillin, like other β-lactam antibiotics, acts by inhibiting the synthesis of bacterial cell walls through interference with the final stage of peptidoglycan synthesis. The bactericidal action causes lysis of growing cells only
Clavulanic acid is a β-lactamase inhibitor and improves the antibacterial spectrum of amoxicillin.

Amoxicillin in combination with clavulanic acid has a wide range of activity which includes ß-lactamase producing strains of both Gram-positive and Gram-negative aerobes, facultative anaerobes and obligate anaerobes, including:

Gram-positive:
Clostridium spp.
Corynebacterium spp.
Peptostreptococcus spp.
Staphylococcus spp. (including β-lactamase producing strains)
Streptococcus spp.

Gram-negative:
Bacteroides spp.
Escherichia coli (including most β-lactamase producing strains)
Campylobacter spp.
Fusobacterium necrophorum
Pasteurella spp.
Proteus spp.

Resistance is shown among *Enterobacter* spp., *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus*. A trend in resistance of *E. coli* is reported.

Susceptibility and resistance patterns can vary with geographical area and bacterial strain, and may change over time.

Amoxicillin/ clavulanate breakpoints (CLSI VET 01S ED5:2020)
E. Coli (dog): sensitive MIC ≤ 8/4 µg/ml
Staphylococcus spp. (dog; cat): sensitive MIC ≤ 0.25/0.12 µg/ml, resistant: ≥ 1/0.5 µg/ml
Streptococcus spp. (cat): sensitive MIC ≤ 0.25/0.12 µg/ml, resistant: ≥ 1/0.5 µg/ml
Pasteurella multocida (cat): sensitive MIC ≤ 0.25/0.12 µg/ml, resistant: ≥ 1/0.5 µg/ml

The main mechanisms of resistance to amoxicillin/clavulanic acid are:
Inactivation by those bacterial beta-lactamases that are not themselves inhibited by clavulanic acid.
Modification of Penicillin-Binding Proteins (PBP), which reduce the affinity of the antibacterial agent for the target proteins (methicillin resistant *S. aureus*, MRSA and *S. pseudintermedius*, MRSP).
Impermeability of bacteria or efflux pump mechanisms may cause or contribute to bacterial resistance, particularly in Gram-negative bacteria. Resistance genes can be located on

chromosomes (mecA, MRSA) or plasmids (LAT, MIR, ACT, FOX, CMY family beta-lactamases) and a variety of resistance mechanisms have emerged.

5.2 Pharmacokinetic particulars

Dogs:

- Amoxicillin
  After dosing of 10 mg/kg amoxicillin, maximum plasma concentrations are reached within 1.0 to 2.0 hours (t_{max}) with a mean half-life of 1.0 – 1.5 hours. C_{max} of 8223 ng/ml and $AUC_{0\text{-last}}$ of 22490 ng.h/ml are observed.
- Clavulanic acid
  After dosing of 2.5 mg/kg clavulanic acid, maximum plasma concentrations are reached within 0.50 to 1.75 hours (t_{max}) with a mean half-life of 0.5 – 0.6 hours. C_{max} of 3924 ng/ml and $AUC_{0\text{-last}}$ of 5284 ng.h/ml are observed.

Amoxicillin is well-absorbed following oral administration. Amoxicillin (pKa 2.8) has a relatively small apparent distribution volume, a low plasma protein binding (34% in dogs) and a short terminal half-life due to active tubular excretion via the kidneys. Following absorption, the highest concentrations are found in the kidneys (urine) and the bile, and then in liver, lungs, heart and spleen. The distribution of amoxicillin to the cerebrospinal fluid is low unless the meninges are inflamed.
Clavulanic acid (pKa 2.7) is also well-absorbed following oral administration. The penetration to the cerebrospinal fluid is poor. The plasma protein binding is approximately 25% and the elimination half-life is short. Clavulanic acid is mainly eliminated by renal excretion (unchanged in urine).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crospovidone
Povidone
Sodium starch glycolate type A
Cellulose microcrystalline
Silica colloidal hydrated
Magnesium stearate
Saccharin sodium
Vanilla flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
Any unused part-tablet should be returned to the blister and used within 36 h.

6.4. Special precautions for storage

Do not store above 30ºC.
Store in the original package.

6.5 Nature and composition of immediate packaging

oPA/Alu/PVC - PVC/Alu heat sealed blister containing 10 tablets each.

Package sizes:
Cardboard box of 10, 30, 50, 100 or 250 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
Spain

8. MARKETING AUTHORISATION NUMBER(S)

VPA10509/025/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/05/2021

10 DATE OF REVISION OF THE TEXT

16/01/2026

PROHIBITION OF SALE, SUPPLY AND/OR USE