ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavusan 250 mg + 62.5 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	250 mg
Clavulanic acid (as potassium clavulanate)	62.5 mg

3. PACKAGE SIZE

10 tablets
30 tablets
50 tablets
100 tablets
250 tablets

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral administration.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}
Any unused part-tablet should be returned to the blister and used within 36 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3041

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavusan

2. QUANTITATIVES PARTICULARS OF THE ACTIVE SUBSTANCES

Amoxicillin 250 mg / Clavulanic acid 62.5 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clavusan 250 mg + 62.5 mg tablets for dogs and cats

2. Composition

Each tablet contains:

Active substances:

Amoxicillin (as amoxicillin trihydrate)	250 mg
Clavulanic acid (as potassium clavulanate)	62.5 mg

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.

3. Target species

Dogs and cats.

4. Indications for use

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.

5. 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.

6. Special warnings

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. The association of 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.
Cross-resistance has been shown between amoxicillin/clavulanic acid and β-lactam antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to β-lactam antibiotics because its effectiveness may be reduced.
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 5.
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 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 require urgent medical attention.
Wash hands after use.
To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space, inserted back into the outer packaging and kept in a safe place out of the sight and reach of children.

Pregnancy and lactation:
The product can be used during pregnancy and lactation.

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.

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

Major incompatibilities:
Not applicable.

7. Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports): gastro-intestinal disorders (vomiting, diarrhoea, anorexia).
Undetermined frequency (cannot be estimated from the available data): allergic reactions (skin reactions, anaphylaxis). In these cases, administration should be discontinued, and a symptomatic treatment given.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

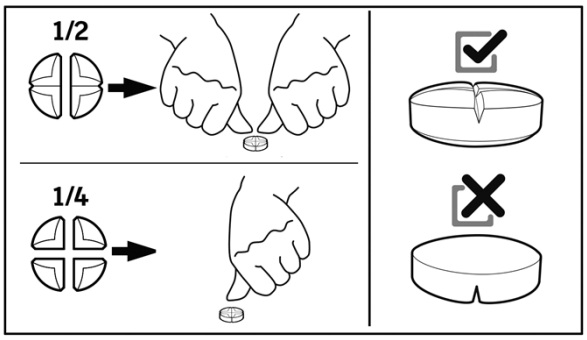
8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30ºC.
Store in the original package. If the tablets are divided, the remaining part-tablets should be kept in the blister pocket.

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

If the tablets are divided, the remaining part-tablets should be kept in the blister pocket and use within 36 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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

Package sizes:
Cardboard box of 10, 30, 50, 100 and 250 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel: +31-(0)348-416945

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

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

Approved: 26 July 2023