ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavudale 400 mg/100 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet contains:
Amoxicillin (as amoxicillin trihydrate) 400 mg
Clavulanic acid (as potassium clavulanate) 100 mg

3. PACKAGE SIZE

12 tablets/24 tablets/120 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Any divided tablet portions remaining after 12 hours should be discarded.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Divided tablets should be stored in the blister pack.
Keep the blister pack in the outer carton.

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

Dechra Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 10434/3011

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavudale

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 tablet contains 400 mg Amoxicillin, 100 mg Clavulanic acid

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use whole or half tablets within 12 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clavudale 400 mg/100 mg Tablets for dogs

2. Composition

1 tablet contains:
Active substances:
Amoxicillin (as amoxicillin trihydrate) 400 mg
Clavulanic acid (as potassium clavulanate) 100 mg

Excipient**:**
Erythrosine (E127) 7.5 mg

Pink, oblong, scored tablets.
The tablet can be divided into halves.

3. Target species

Dogs.

4. Indications for use

For the treatment of bacterial infections susceptible to amoxicillin in combination with clavulanic acid where clinical experience and/or sensitivity testing indicates the veterinary medicinal product as the drug of choice.
Uses include:
Skin infections (including deep and superficial pyodermas) associated with *Staphylococcus* spp. and *Streptococcus* spp.;
Infections of the oral cavity (mucous membrane) associated with *Clostridium* spp., *Trueperella* spp. (previously *Corynebacterium* spp.), *Staphylococcus* spp., *Streptococcus* spp., *Bacteroides* spp. and *Pasteurella* spp.;
Urinary tract infections associated with *Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli* and *Proteus mirabilis*;
Respiratory tract infections associated with *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.;
Gastrointestinal infections associated with *Escherichia coli* and *Proteus mirabilis*.

5. Contraindications

Do not use in rabbits, guinea pigs, hamsters and gerbils.
Do not use in animals with known hypersensitivity to penicillin or substances of the β-lactam group or any of the excipients.
Do not use in animals with either little or no urination associated with renal dysfunction.
Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.

6. Special warnings

Special precautions for safe use in the target species:

In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated.
Use of the veterinary medicinal product should be based on susceptibility testing and should take into account official national and regional policies with respect to the use of broad spectrum antibiotics. Do not use in cases of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as a single substance. Use of the veterinary medicinal product deviating from the instructions given in this package leaflet may increase the prevalence of bacteria resistant to amoxicillin and clavulanic acid, and may decrease the effectiveness of treatment with other β-lactam antibiotics, due to the potential for cross-resistance.

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 veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.
- Handle this veterinary medicinal 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 package leaflet or 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.
- In order to avoid any accidental ingestion, store tablets out of reach of animals.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Caution is advised on the use of the veterinary medicinal product in small herbivores other than those listed in the section on Contraindications.

Pregnancy and 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 or cats. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Bacteriostatic antibiotics (e.g. 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 (diarrhoea and vomiting) may occur more frequently after overdose of the veterinary medicinal product.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[a], Diarrhoea[a]
Undetermined frequency (cannot be estimated from the available data)	Blood dyscrasia (blood abnormality), Colitis Anaphylaxis (severe allergic reaction), Allergic skin reaction

[a] Mild. In these cases, discontinue administration and give symptomatic therapy.

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

Follow the dosage instructions given by your veterinary surgeon.
For oral administration only. The dosage rate is 10 mg amoxicillin/2.5 mg clavulanic acid/kg body weight twice daily.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
The following table is intended as a guide to dispensing the veterinary medicinal product at the standard dose rate of 10 mg amoxicillin/2.5 mg clavulanic acid/kg body weight twice daily.

Body weight (kg)	Number of tablets twice daily
> 30 to ≤ 40	1
> 40 to ≤ 60	1½
> 60 to ≤ 80	2

In refractory cases the dose may be doubled to 20 mg amoxicillin/5 mg clavulanic acid/kg body weight twice daily.

Duration of therapy:
Routine cases involving all indications:
The majority of routine cases respond to between 5 and 7 days of therapy. Lack of effect after 5-7 days of treatment necessitates renewed examination.

Chronic or refractory cases:
In chronic cases, longer courses of antibacterial therapy may be required. In such circumstances, overall treatment length is at the clinician's discretion, but must be long enough to ensure complete resolution of the bacterial disease.

9. Advice on correct administration

The tablets may be added to a little food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25ºC.
Divided tablets should be stored in the blister pack.
Keep the blister pack in the outer carton.
Shelf life after first opening the immediate packaging: 12 hours
Any divided tablet portions remaining after 12 hours should be discarded.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and the carton after Exp. The expiry date refers to the last day of that month.

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 10434/3011

Blister packs consisting of orientated Polyamide/Aluminium/Polyvinyl chloride film, heat sealed with aluminium foil (25 µm) in strips of 6 tablets. Cartons containing 12, 24 or 120 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW

Manufacturer responsible for batch release:
Laboratorio Reig Jofré SA
Jarama s/n Polígono Industrial
45007 Toledo
Spain

Genera Inc.,
Svetonedeljska cesta 2,
Kalinovica,
10436 Rakov Potok,
Croatia

17. Other information

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