ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavudale 200 mg/50 mg
Tablets for dogs

Amoxicillin 200 mg, Clavulanic acid 50 mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains:
Active substances:
Amoxicillin (as amoxicillin trihydrate) 200 mg
Clavulanic acid (as potassium clavulanate) 50 mg
Excipient:
Erythrosine (E127) 3.75 mg

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

12 tablets/24 tablets/120 tablets

5. TARGET SPECIES

Dogs.

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
User warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP: (month/year)

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Divided tablets should be stored in the blister pack.
Any divided tablet portions remaining after 12 hours should be discarded.
Keep the blister pack in the outer carton.

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

Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 10434/4051

17. MANUFACTURER'S BATCH NUMBER

Lot: (number)

IE only:

VPA22622/005/002

POM

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavudale 200 mg/50 mg
Tablets
For dogs

Amoxicillin 200 mg, Clavulanic acid 50 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited

3. EXPIRY DATE

EXP: (month/year)

4. BATCH NUMBER

Lot: (number)

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Clavudale 200 mg/50 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:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavudale 200 mg/50 mg tablets for dogs

Amoxicillin 200 mg, Clavulanic acid 50 mg

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 tablet contains:
Active substances:
Amoxicillin (as amoxicillin trihydrate) 200 mg
Clavulanic acid (as potassium clavulanate) 50 mg
Excipient:
Erythrosine (E127) 3.75 mg
Pink, oblong, scored, meat flavoured tablets.

4. INDICATIONS

For the treatment of bacterial infections susceptible to amoxicillin in combination with clavulanic acid where clinical experience and/or sensitivity testing indicates the 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., *Corynebacterium* spp., *Staphylococcus* spp., *Streptococcus* spp., *Bacteroides* spp. and *Pasteurella* spp.;
Urinary tract infections associated with *Staphylococcus* spp., *Streptococcus*., *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. ADVERSE REACTIONS

Mild gastrointestinal signs (diarrhoea and vomiting) may occur after administration of the product.
Allergic reactions (skin reactions, anaphylaxis), blood dyscrasia and colitis may occasionally occur. In these cases, discontinue administration and give symptomatic treatment.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE 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. The tablet can be divided into halves.

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 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
> 8 to ≤ 10	½
> 10 to ≤ 20	1
> 20 to ≤ 30	1½
> 30 to ≤ 40	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 PERIOD

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.
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 WARNINGS

Special precautions for use in animals:
Caution is advised on the use of the product in small herbivores other than those listed in the section 'Contraindications'.
In animals with hepatic and renal dysfunction, the dosing regimen should be carefully evaluated.
Use of the 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 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.

User warnings:
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 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 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 (symptoms, emergency procedures, antidotes):
Mild gastrointestinal symptoms (diarrhoea and vomiting) may occur more frequently after overdose of the product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

IE only:

VPA22622/005/002

POM

Prescription Only Medicine

For animal treatment only.
To be supplied only on veterinary prescription.
Pack sizes: 12, 24 or 120 pack consisting of 2, 4 or 20 blisters, each containing 6 tablets per blister.
Not all pack sizes may be marketed.

Approved: 07/01/21

D Austin