ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50 mg Chewable Flavoured Tablets for Cats and Dogs
Amoxicillin and Clavulanic Acid.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Amoxicillin (as Amoxicillin Trihydrate)	40 mg
Clavulanic acid	10 mg

3. PHARMACEUTICAL FORM

Chewable Tablet.
The tablets can be divided into equal halves.

4. PACKAGE SIZE

- 20 tablets
- 50 tablets
- 100 tablets
- 200 tablets
- 250 tablets
- 500 tablets.

5. TARGET SPECIES

Cats and Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Discard any unused halved tablets immediately.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in a dry place.

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

(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Newry

(UK) Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4317

17. MANUFACTURER'S BATCH NUMBER

BN

POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blisters}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50 mg Chewable Flavoured Tablets for Cats and Dogs
Amoxicillin and Clavulanic Acid.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

BN

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Noroclav 50 mg Chewable Flavoured Tablets for cats and 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:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufacturer Responsible for Batch release:
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclav 50 mg Chewable Flavoured Tablets for cats and dogs.
Amoxicillin and Clavulanic Acid.

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

Each tablet contains:

Amoxicillin (as Amoxicillin Trihydrate)	40 mg
Clavulanic acid (as Potassium Clavulanate)	10 mg

Pale brown circular tablet with a score line and embossed with ‘50’ on opposing faces.

4. INDICATION(S)

Treatment of the following infections caused by beta-lactamase producing strains of bacteria sensitive to amoxicillin in combination with clavulanic acid:

Skin infections (including superficial and deep pyodermas) caused by *Staphylococcus* spp.
Urinary tract infections caused by *Staphylococcus* spp or *Escherichia coli*.
Respiratory tract infections caused by *Staphylococcus* spp.
Enteritis caused by *Escherichia coli*.
Dental infections (e.g. gingivitis).

It is recommended to carry out suitable tests for sensitivity when initiating the treatment. The treatment should only proceed if sensitivity is proven to the combination.

5. CONTRAINDICATIONS

The product should not be given to rabbits, hamsters, guinea pigs or gerbils.

Do not use in animals with known hypersensitivity to penicillin, other beta-lactams or any of the excipients. Do not use in animals with serious dysfunction of the kidneys accompanied by anuria or oliguria.
Do not use where resistance to this combination is known to occur.
Do not administer to horses and ruminating animals.

6. ADVERSE REACTIONS

Hypersensitivity reactions to penicillins may occur in treated animals.
Allergic reactions (e.g. skin reactions, anaphylaxis) may occasionally occur. In case of occurrence of allergic reaction, the treatment should be withdrawn.
Very rarely, (less than 1 animal in 10,000 animals treated, including isolated reports), use of the product may result in gastro-intestinal disorders (vomiting, diarrhoea, anorexia).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats and Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administration: by the oral route.
Dosage rate: total 12.5 mg of combined actives/kg bw. (equal to 10 mg of amoxicillin + 2.5 mg of clavulanate/kg bw).
Dosage frequency: The following table is intended as a guide to dispensing at the standard dose rate of 12.5 mg/kg bw, twice daily.
To ensure a correct dosage, bodyweight should be determined as accurately as possible.

50 mg tablet strength:

Body weight (kg)	Number of tablets to be administered twice daily
[1.0- 2.0]	½
[2.1- 4.0]	1
[4.1- 6.0]	1 ½
[6.1- 8.0]	2
>8	Use 250 or 500 mg tablets

If the dog or cat does not accept the tablet from hand or bowl, then the tablets may be crumbled and added to a little food.
The majority of routine cases respond after between 5 and 7 days therapy. If no improvement is observed after 5 – 7 days, the diagnosis should be re-assessed.

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.
If no improvement is observed after two weeks, the diagnosis should be re-assessed.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing or overdosing.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

Do not store above 30°C.
Store in a dry place.
Discard any unused halved tablets immediately.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after “EXP”.

12. SPECIAL WARNINGS

Special precautions for use in animals

Whenever possible, the product 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 beta-lactam antimicrobials and may decrease the effectiveness of treatment with other classes of antimicrobials due to the potential for cross resistance.
Chloramphenicol, macrolides, sulfonamides and tetracyclines may inhibit the antibacterial effect of penicillins because of the rapid onset of bacteriostatic action.
The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.
Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
In pregnant and lactating animals, use only according to the benefit/risk assessment by the responsible veterinarian.In animals with hepatic and renal failure, the dosing regimen should be carefully evaluated.
Caution is advised in their use in small herbivores.
Official and regional antimicrobial policies should be taken into account.

Overdose
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.
Symptomatic treatment should be initiated when necessary. Mild gastrointestinal symptoms (diarrhoea, nausea and vomiting) may occur more frequently after overdose of the product.

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.

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

July 2019

15. OTHER INFORMATION

LEGAL CATEGORY:

POM-V

PACKAGE QUANTITIES:

Blisters (aluminium/aluminium): 20, 50, 100, 200, 250 and 500 tablets in outer packages with blister strips containing 10 tablets each.
Not all pack sizes may be marketed.

FURTHER INFORMATION
Amoxicillin is a broad-spectrum antibiotic active against a wide range of Gram-positive and Gram-negative bacteria. However, many clinically important bacteria produce beta-lactamase enzymes which destroy this antibiotic. Clavulanic acid inactivates these enzymes, rendering the organisms susceptible to the amoxicillin.

FOR ANIMAL TREATMENT ONLY.

Approved: 30 July 2019