ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{10 ml polyethylene syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albiotic 330 mg / 100 mg Intramammary Solution
Lincomycin+Neomycin

2. QUANTITY OF THE ACTIVE SUBSTANCES

Each 10 ml syringe:

Active substances
Lincomycin (as Lincomycin Hydrochloride) – 330 mg
Neomycin (as Neomycin Sulfate) – 100 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

Intramammary administration.

5. WITHDRAWAL PERIOD(S)

Milk: 84 hours
Meat: 3 days

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

Exp {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albiotic 330 mg / 100 mg Intramammary Solution
Lincomycin+Neomycin

2. STATEMENT OF ACTIVE SUBSTANCES

Each 10 ml syringe:

Active substances
Lincomycin (as Lincomycin Hydrochloride) – 330 mg
Neomycin (as Neomycin Sulfate) – 100 mg

3. PHARMACEUTICAL FORM

Intramammary solution

4. PACKAGE SIZE

1 to 100 x 10 ml

5. TARGET SPECIES

Lactating cows.

6. INDICATION(S)

Read the package label before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package label before use

8. WITHDRAWAL PERIOD(S)

Milk: 84 hours
Meat: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with the solution. Wash hands and any exposed skin immediately after use.

10. EXPIRY DATE

Exp {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Protect from freezing. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

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

Marketing authorisation
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4035

17. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Albiotic 330 mg / 100 mg Intramammary Solution

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen, Belgium

Manufacturer responsible for batch release
Biovet Joint Stock Company
39, Petar Rakov Str.
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albiotic 330 mg / 100 mg Intramammary Solution
Lincomycin / Neomycin

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

Each 10 ml syringe contains:
Active substances

Lincomycin (as lincomycin hydrochloride)	330 mg
Neomycin (as neomycin sulphate)	100 mg

Excipient

Disodium edetate	5 mg

4. INDICATION(S)

For the treatment of mastitis in lactating cattle. The product is effective against *Staphylococcus species* (both penicillinase and non-penicillinase producers) including *Staphylococcus aureus, Streptococcus species* including *Streptococcus agalactiae, Streptococcus dysgalactiae* and *Streptococcus uberis*, and coliform bacteria including *Escherichia coli*.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

Contact your veterinarian if you notice any adverse reactions. This also applies to adverse reactions that are not already listed in this leaflet or if you believe that the medicinal product has not worked according to the recommendations.

7. TARGET SPECIES

Lactating cows.

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

Intramammary infusion only, taking aseptic precautions.
Infuse one syringe (10 ml product) into each affected quarter. Repeat this treatment immediately after each of the next two 12 hourly milkings, to give a total of three infusions per infected quarter.

9. ADVICE ON CORRECT ADMINISTRATION

The syringe must only be used once.
Where necessary, wash teats or whole udder thoroughly with warm water containing a suitable dairy disinfectant and dry them thoroughly. Milk out the udder completely. Disinfect teat end with a pad of alcohol or other suitable disinfectant. Use a separate pad for each teat.

Directions for insertion are as follows:
Full insertion: remove the white end cap by pulling straight up. Gently insert full cannula into the teat canal; carefully infuse the product.

Partial insertion: remove the white end cap by pulling straight up. Gently insert cannula 1/8" into the teat canal; carefully infuse the product.

Push plunger to dispense entire contents and massage the quarter to distribute the product into the milk cistern. Following infusion, it is advisable to dip all teats in an approved teat dip.

10. WITHDRAWAL PERIOD(S)

Milk: 84 hours
Meat: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 30°C. Protect from freezing. Protect from light.

Keep the syringe in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Expires End.

12. SPECIAL WARNINGS

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with the solution. Wash hands and any exposed skin immediately after use.

Interaction with other medicinal products and other forms of interaction:
This product should not be used concomitantly with macrolides e.g. erythromycin, because lincomycin and the macrolides antagonise each other at the site of action, the 50S ribosomal sub-unit.

Overdose (symptoms, emergency procedures, antidotes):
The product is well tolerated. In the event of accidental overdose, it is unlikely that any local or systemic adverse effects will occur in the animal, however, any signs of adverse effect should be immediately reported to the veterinarian concerned.

Major incompatibilities:
None known

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

Any unused product or waste material should be disposed of in accordance with national requirements.

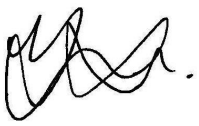
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION>

For animal treatment only.
Supplied in cartons containing 24 x 10 ml syringes.

POM-V
To be supplied only on veterinary prescription.

Vm 30282/4035



Approved: 17 September 2019