SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albiotic 330 mg / 100 mg Intramammary Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances
per syringe (10 ml)

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

Excipients

Disodium edetate	5 mg

For the full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Intramammary solution

4. CLINICAL PARTICULARS

4.1 Target species

Lactating cow

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

None

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation, or lay

No restrictions.

4.8 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.

4.9 Amounts to be administered and administration route

Dosage: 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.

Administration: by intramammary infusion only, taking aseptic precautions. 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:
a. Full insertion: remove the white end cap by pulling straight up. Gently insert full cannula into the teat canal; carefully infuse the product.
b. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Milk: 84 hours

Meat: 3 days

5. PHARMACOLOGICAL PROPERTIES

The product contains the active ingredients lincomycin hydrochloride and neomycin sulphate in a sterile aqueous vehicle.

5.1 Pharmacodynamic properties

Lincomycin is a lincosaminide antibiotic derived from *Streptomyces lincolnensis*. It possesses specific activity against Gram-positive bacteria, particularly Staphylococcus species and Streptococcus species and has little or no activity against Gram-negative bacteria such as *E.coli* (except anaerobes). Lincomycin has good activity against mycoplasma. Lincomycin binds to the 50S sub-unit of the bacterial ribosome, thereby inhibiting protein synthesis of the cell. It is generally regarded as a bacteriostatic compound.

Neomycin is an aminoglycoside antibiotic derived from *Streptomyces fradiae*. It has a broad spectrum of activity against both Gram-positive bacteria, including Staphylococcus species and Streptococcus species, and Gram-negative bacteria, including *Escherichia coli*. It is more active against Staphylococcus species than against Streptococcus species. Neomycin binds to the 30S sub-unit of the bacterial ribosome resulting in a malconformation of binding ribosomal protein due to errors in reading the amino acid coding of the mRNA. Neomycin thus compromises translation and hence bacterial protein synthesis.
At high concentrations, the aminoglycosides have also been shown to damage the cellular membrane of bacteria and hence are generally regarded as possessing both bacteriostatic and bactericidal properties.

In vitro studies have demonstrated that lincomycin and neomycin in combination have bactericidal activity against *Staphylococcus aureus* and *Escherichia coli* and bacteriostatic activity against streptococci. The combination has also demonstrated synergy against *Staphylococcus aureus*.

Lincomycin, neomycin and the combination have been shown to be active against both penicillinase and non-penicillinase producing staphylococci.

5.2 Pharmacokinetic particulars

After recommended infusion of the product, the following mean concentrations of lincomycin and neomycin were measured in individual treated quarters:

Antibiotic	Concentrations (µg/ml) / Time after first infusion			
	12 hours[1]	24 hours[2]	36 hours	48 hours
Lincomycin	52.7	53.5	56.9	4.6
Neomycin	22.2	29.7	28.0	4.9

[1] immediately before second infusion
[2] immediately before third (last) infusion

Antibiotic levels in milk above the MIC-values for target pathogens are sustained for the full dosage period and for at least 12 hours thereafter.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Edetate
Hydrochloric Acid
Sodium Hydroxide
Water for injections

6.2 Major incompatibilities

None known

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

10 ml polyethylene syringes (plastets), packaged as 1 to 100 plastets in an outer cardboard box.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 30282/4035

9. DATE OF FIRST AUTHORISATION

04 January 2000

10. DATE OF REVISION OF THE TEXT

August 2019

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