SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albiotic 330 mg/100 mg Intramammary Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL syringe contains:

Active substances:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Disodium Edetate	5 mg
Hydrochloric Acid	
Sodium Hydroxide	
Water for injections	

Clear, colourless to slightly yellow liquid.

3. CLINICAL INFORMATION

3.1 Target species

Lactating cows.

3.2 Indications for use for each target species

For the treatment of mastitis in lactating cattle. The veterinary medicinal 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*.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact with the veterinary medicinal product. Wash hands and any exposed skin immediately after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Lactating cows:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

This veterinary medicinal 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.

3.9 Administration routes and dosage

Administration
By intramammary infusion only, taking aseptic precautions.

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. The syringe should 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Milk: 84 hours.
Meat and offal: 3 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ51RF03.

4.2 Pharmacodynamics

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 *Escherichia 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 malconfirmation 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 concentration, 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.*

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 30 °C.
Do not freeze.
Keep the syringe in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

10 ml syringe with a high-density polyethylene (HDPE) barrel and plunger rod, a bromobutyl rubber plunger and a low-density polyethylene (LDPE) cap.

Pack size:
Cardboard box containing 24 x 10 ml syringes.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER

Vm 30282/4035

8. DATE OF FIRST AUTHORISATION

04 January 2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Approved 16 June 2026

Gavin Hall