PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 10 or 20 single use syringes and 10 or 20 disinfecting towels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrolexin intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each 10 g (12 ml) intramammary syringe contains:
Active substances:
200 mg cefalexin (equivalent to 210 mg cefalexin monohydrate)
100 000 I.U. kanamycin monosulfate

3. PACKAGE SIZE

10 x 10 g (including 10 disinfecting towels)
20 x 10 g (including 20 disinfecting towels)

4. TARGET SPECIES

Cattle (lactating cows)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 10 days.
Milk: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS ‘’READ THE PACKAGE LEAFLET BEFORE USE’’

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/5015
Vm 61700/3019

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

One single use syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrolexin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cefalexin 200 mg
Kanamycin monosulfate100 000 I.U.

10g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Ubrolexin Intramammary Suspension for Lactating Dairy Cows

2. Composition

Each 10 g (12 ml) intramammary syringe contains:

Active substances:
200 mg cefalexin (equivalent to 210 mg cefalexin monohydrate)
100 000 I.U. kanamycin monosulfate

Off-white, smooth oily paste.

3. Target species

Cattle (lactating cows)

4. Indications for use

Treatment of clinical mastitis in lactating dairy cows for bacteria susceptible to the combination of cefalexin and kanamycin such as *Staphylococcus aureus* (see section 15: Other information), *Streptococcus dysgalactiae*, *Streptococcus uberis* and *Escherichia coli*.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances, or to any of the excipients.
Do not use in non-lactating cattle.
Do not use in the case of known resistance of cefalexin and/or kanamycin.

6. Special warnings

Special precautions for safe use in the target species:
The veterinary medicinal product should be used for treatment of clinical mastitis only.
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional and farm level) epidemiological information about susceptibility of the target bacteria as well as by considering official national antimicrobial policies.
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to cefalexin and kanamycin and may decrease the effectiveness of treatment with other cephalosporins or aminoglycosides due to the potential for cross-resistance.

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 sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity to cefalexin and kanamycin should avoid contact with the veterinary medicinal product. Take all recommended precautions. Handle the veterinary medicinal product with great care to avoid exposure by accidental contact with the skin. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. Wash exposed skin after use. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:
Laboratory studies inanimals have not produced any evidence of teratogenic effects. Field studies in dairy cows have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects. Can be used during pregnancy. Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
In general, combination with bacteriostatic antimicrobials should be avoided.
In case of resistance to cefalexin, cross-resistance with other cephalosporins is likely to occur.
In case of resistance to kanamycin, cross-resistance occurs between kanamycin, neomycin and paromomycin. A one-way resistance with streptomycin is known.

Overdose:
No available data.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramammary use.
Treat the infected quarter(s) twice, leaving an interval of 24 hours between treatments. Use the contents of one syringe (containing 200 mg cefalexin as

monohydrate and 100 000 I.U. kanamycin as monosulfate) per quarter per treatment. Each syringe is for single use only.

9. Advice on correct administration

Before infusion, the udder should be milked out completely, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle.

10. Withdrawal periods

Meat and offal: 10 days.
Milk: 5 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and syringe after Exp. The expiry date refers to the last day of the month.
The veterinary medicinal product does not require any special storage conditions.

12. Special precautions for disposal

Medcines should not be disposed of via wastewater.

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. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 61700/5015
Vm 61700/3019

10 x intramammary syringes of 10 g (12 ml), including 10 disinfecting towels.
20 x intramammary syringes of 10 g (12 ml), including 20 disinfecting towels.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
+353 1 291 3985

Manufacturer responsible for batch release:
Univet Ltd
Tullyvin
Cootehill, Co. Cavan
Ireland

17. Other information

POM-V

The combination of cefalexin and kanamycin showed a bactericidal mode of action against *Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus uberis* and *Escherichia coli.* The effect of cefalexin and kanamycin in combination is mainly time-dependent.

Minimum inhibitory concentration, checkerboard analysis, kill kinetic and post antibiotic effect data demonstrate an advantage of the combination by broadening the activity spectrum and by showing synergistic antibacterial activity: the effect of cefalexin is enhanced by kanamycin and vice versa.

Staphylococcus aureus has the potential to evade the immune system and establish deep-seated infection in the mammary gland. Thus, as is the case for other intramammary veterinary medicinal products, bacteriological cure rates in the field are expected to be low. *In vitro* studies have demonstrated that isolates (2002-2004 and 2009-2011) of *S. aureus* are susceptible to the combination of active substances.

In vitro studies demonstrate that isolates of *S. agalactiae (collected in 2004)* and coagulase-negative staphylococci (collected in 2004 and 2009-2011) are susceptible to the combination of active substances.

Gavin Hall
Approved: 28 November 2025