LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box (10 and 20 syringes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrolexin intramammary suspension for lactating dairy cows
Cefalexin monohydrate/ Kanamycin monosulphate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 10 g intramammary syringe contains:
Cefalexin (as monohydrate): 200 mg
Kanamycin (as monosulphate): 100,000 I.U.

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

10 x 10 g (including 10 teat wipes)
20 x 10 g (including 20 teat wipes)

5. TARGET SPECIES

Cattle (lactating dairy cows)

6. INDICATIONS

Treatment of clinical mastitis in lactating dairy cows for bacteria susceptible to the combination of cefalexin and kanamycin such as *Staphylococcus aureus*, *Streptococcus dysgalactiae*, *Streptococcus uberis* and *Escherichia coli*.

7. METHOD AND ROUTE OF ADMINISTRATION

Treat the infected quarter(s) twice, leaving an interval of 24 hours between treatments. Use the contents of one syringe per quarter per treatment.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Meat and offal: 10 days
Milk: 5 days

9 SPECIAL WARNING(S), IF NECESSARY

User warnings/ Disposal: read package leaflet.

10 EXPIRY DATE

EXP {month/year}

11 SPECIAL STORAGE CONDITIONS

Not applicable.

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

User warnings/ 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4306

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrolexin intramammary suspension for lactating dairy cows
Cefalexin monohydrate/ Kanamycin monosulphate

2. QUANTITY THE ACTIVE SUBSTANCES

Cefalexin (as monohydrate): 200 mg
Kanamycin (as monosulphate): 100,000 I.U.

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

10 g

4. ROUTE OF ADMINISTRATION

For single intramammary use.

5. WITHDRAWAL PERIOD

Meat and offal: 10 days
Milk: 5 days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Ubrolexin intramammary suspension for lactating dairy cows

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

Marketing authorisation holder

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer for the batch release

Univet Ltd
Tullyvin
Cootehill, Co. Cavan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubrolexin intramammary suspension for lactating dairy cows
Cefalexin monohydrate/ Kanamycin monosulphate

3. STATEMENT OF THE ACTIVE SUBSTANCES

Each 10 g (12 ml) intramammary syringe contains:
Cefalexin (as monohydrate): 200 mg
Kanamycin (as monosulphate): 100,000 I.U.
Off-white, oily paste suspension.

4. INDICATIONS

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 lactating dairy cows with a known hypersensitivity to cefalexin and/or kanamycin.
Do not use in non-lactating cattle.
Do not use in the case of known resistance of cefalexin and/or kanamycin.

6. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (lactating dairy cows)

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

For 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 monosulphate) 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 PERIOD

Meat and offal: 10 days
Milk: 5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date (EXP) stated on the carton and syringe.

12. SPECIAL WARNINGS

Precautions for use in animals
Recommendations for prudent use:
The product should be used for treatment of clinical mastitis only.
Use of the 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 taking into account official national antimicrobial policies.

Inappropriate use of the 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.

Precautions to be taken by the person administering the product
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.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Take all recommended precautions. Handle this product with great care to avoid exposure by accidental contact with the skin. It is recommended to wear gloves when handling or administering the product . Wash exposed skin after use.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Use during pregnancy and lactation
Pregnancy
Studies in laboratory animals have not produced any evidence of teratogenic effect. Field studies in dairy cows have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effect. The product can be used in pregnant cows.

Lactation
The product is intended for use during lactation.

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.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

<MM/YYYY>

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

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 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.

Package sizes:
10 x intramammary syringes of 10 g (12 ml), including 10 teat wipes
20 x intramammary syringes of 10 g (12 ml), including 20 teat wipes
Not all pack sizes may be marketed.

Approved: 07 November 2018