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R Čefalonium 250mg Intramammary suspension (Vet)

IIII Cepravin[®] Dry Cow

NOT FOR HUMAN USE; FOR ANIMAL TREATMENT ONLY

SCHEDULE H PRESCRIPTION DRUG – CAUTION Not to be sold by retail without the prescription of a Registered Veterinary Practitioner only.

Each 3G syringe contains: Cefalonium dihydrate – 250 mg

Pharmaceutical form:

Intramammary suspension

Indications:

The veterinary medicinal product is recommended to treat existing sub-clinical infections and to prevent new infections which occur during the dry period caused by the following cefalonium-sensitive organisms: *Corynebacterium bovis, Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus uberis, Echerichia coli, Klebsiella spp., and Arcanobacterium pyognes.*

Contraindications:

Do not use in lactating cow. Not intended for use within 54 days of calving. Not to be administered to animals which are known to be hypersensitive to cephalosporin antibiotics and β-lactam antibiotics.

Target species: Dairy cattle (non-lactating)

Dosage for each Species:

For intramammary infusion

One syringe (250 mg cefalonium) is infused into each quarter of the udder.

Posology and method of administration:

The content of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation. Before infusion, the teat should be thoroughly cleaned and disinfected. Avoid contamination of the nozzle after removing the cap. After infusion it is advisable to dip the teats in an antiseptic preparation specifically designed for the purpose.



 After milking is complete thoroughly clean and disinfect the end of the teat (e.g. with cotton wool soaked in methylated spirit)











- 2 (i) Option 1: For short nozzle intramammary administration hold the barrel of the syringe and the base of the cap in one hand and twist off the small upper part of the cap above
 - hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the syringe). Take care not to contaminate the short exposed part of nozzle.
- 2 (ii) Option 2: For full nozzle intramammary administration remove the cap fully by holding the barrel of the syringe firmly in one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.
 - 3. Insert the nozzle into the teat canal and apply steady pressure on the syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.
 - 4. Finally immerse the teats in a teat dip.





Adverse reactions:

Special warning for each target species:

No special warnings are considered necessary.

Overdose[.]

Repeated doses in cattle on three consecutive days did not demonstrate or produce any adverse effects.

Withdrawal periods:

Milk: 96 hours after calving, if cows calve at least 54 days after treatment, milk for human consumption may be taken after 54 days plus 96 hours after treatment.

Meat and offal: Zero days. The absence of antibiotic should be confirmed by testing before its milk is used for human consumption. This is advisable because of variation in the milking cow's ability to excrete antibiotics from dry cow products. In cows suffering from hypocalcaemia, it may be necessary to discard milk for a longer period.

Special Warning(s):

Special precautions for use in animals

Use of the product should be based on susceptibility testing of bacteria isolated from milk samples from the animal. If this is not possible, therapy should be based on local (regional, farm level)epidemiological information about susceptibility of target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefalonium and may decrease the effectiveness of treatment with other beta lactams. Dry cow therapy protocols should take local and national policies on antimicrobial use into consideration, and undergo regular veterinary review. The feeding to calves of milk containing residues of cefalonium that could select for antimicrobial resistant bacteria (e.g. production of beta-lactamases) should be avoided up to the end of the milk withdrawal period, except during the colostral phase.

The efficacy of the product is only established against the pathogens mentioned in Section "Indications for use". Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, particularly Pseudomonas aeruginosa, can occur after drying off. Good hygienic practices should be thoroughly respected in order to reduce this risk.

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

Handle this product with great care to avoid exposure, taking all recommended precautions. Wash hands after use.

Penicillin and cephalosporins may cause sensitization (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin 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 sensitized, or if you have been advised not to work with such preparations.

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

Use during pregnancy and lactation:

Intended for use during last trimester of pregnancy once the lactating cow has been dried off. There is no adverse treatment effect on the foetus.

Not to be used in cows those are lactating. List of excinients

Gel base

The gel base consists of: Aluminium distearate Liquid paraffin Ph Eur

Special Precautions for the disposal of unused product or waste material, if any:

Dispose of any unused product and empty syringes in accordance with guidance from your local waste regulation authority.

Special Storage Condition:

Do not store above 30°C Keep out of the reach and sight of children.

Shelf Life : 3 years

Package Size: Boxes of 20 syringes Herd Packs of 120 syringes (6 boxes of 20) Dairy Packs of 160 syringes (8 boxes of 20)

Manufactured by:

Intervet International GmbH, Feldstrasse 1A, D-85716, Unterschleissheim, Germany

Imported and Marketed by: Intervet India Pvt. Ltd.



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