PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acticarp 50 mg/ml Solution for Injection for Cattle

Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains 50 mg carprofen and ethanol anhydrous.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 vial of 50 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous or intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 21 days.
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening of the container: 28 days.
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

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

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

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4005

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acticarp 50 mg/ml Solution for Injection for Cattle

Carprofen

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml solution for injection contains 50 mg carprofen and ethanol anhydrous.

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

SC / IV

5. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 21 days.
Milk: zero hours.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}
Once broached use by 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:
Acticarp 50 mg/ml Solution for Injection for Cattle

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

Marketing authorisation holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

or

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
HA1 4HF Middlesex
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acticarp 50 mg/ml Solution for Injection for Cattle

Carprofen

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per ml:

Active substance:
Carprofen 50 mg

Excipients:
Ethanol anhydrous

The product is a clear, pale straw yellow solution.

4. INDICATION(S)

The product is indicated as an adjunct to antimicrobial therapy to reduce clinical signs in acute infectious respiratory disease and acute mastitis in cattle.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals suffering from cardiac, hepatic or renal impairment.
Do not use in animals suffering from gastro-intestinal ulceration or bleeding.
Do not use where there is evidence of a blood dyscrasia.

6. ADVERSE REACTIONS

Studies in cattle have shown that a transient local reaction may form at the site of the injection.
If you notice any serious effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

The product should be given as a single subcutaneous or intravenous injection at a dosage of 1.4 mg carprofen/kg body weight (1 ml/35 kg) in combination with antibiotic therapy, as appropriate.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Meat and offal: 21 days.
Milk: zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the outer carton and immediate label. The expiry date refers to the last day of that month.
Shelf life after first opening of the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.
Do not exceed the stated dose or the duration of treatment.
Do not administer other NSAID's concurrently or within 24 hours of each other.

Special precautions to be taken by the person administering the product:
Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies.
Avoid contact with skin and eyes. Should this occur, wash the affected areas immediately. Seek medical attention if irritation persists.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy:
In the absence of any specific studies in pregnant cattle, use only after a risk/benefit assessment has been performed by the attending veterinary surgeon.

Interaction with other medicinal products and other forms of interaction:
No significant drug interactions have been reported for carprofen. During clinical studies in cattle four different antibiotic classes were used, macrolides, tetracyclines, cephalosporins and potentiated penicllins without known interactions. However, in common with other NSAIDs, carprofen should not be administered simultaneously with another product of the NSAID or glucocorticoid class. Animals should be carefully monitored if carprofen is administered simultaneously with an anticoagulant.
As NSAID therapy can be accompanied by GI or renal impairment, adjunctive fluid therapy should be considered especially in the case of acute mastitis treatment.

NSAID's are highly bound to plasma proteins and may compete with other highly bound drugs, such that concomitant administration may result in toxic effects.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):
In clinical studies, no adverse signs were reported after intravenous and subcutaneous administration of up to 5 times the recommended dose.
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAID's, should be applied.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

1 vial of 50 ml.

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

Approved 09 February 2017