ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

CARTON 50ml/100 ml/250 ml
LABEL 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RIMADYL - Cattle 50 mg/ml solution for injection.
Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Carprofen 50mg/ml
Excipients: Ethanol 0.1 ml/ml, Benzyl Alcohol 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

For cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous or intravenous use.
Read the package leaflet before use.

8. 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} Once broached, use within 28 days.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

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

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4118

17. MANUFACTURER'S BATCH NUMBER

LOT

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL 50 ml/100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RIMADYL - Cattle 50 mg/ml solution for injection
Carprofen

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Carprofen 50 mg/ml

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

50 ml
100 ml

4. ROUTE(S) OF ADMINISTRATION

SC, IV

5. WITHDRAWAL PERIOD

Meat and offal: 21 days
Milk: Zero hours

6. BATCH NUMBER

LOT

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
RIMADYL - Cattle 50 mg/ml solution for injection.

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

Marketing authorisation holder
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Bela-Pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RIMADYL - Cattle 50 mg/ml solution for injection.

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

Active substance: Carprofen 50 mg/ml
Excipients: Ethanol 0.1 ml/ml, Benzyl Alcohol 10 mg/ml

4. INDICATION(S)

Rimadyl solution 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 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.
Do not use in known cases of hypersensitivity to the active substance or to the excipients.
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

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 or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

The recommended dose is 1.4 mg/ml carprofen / kg body weight (1 ml/35 kg) in combination with antibiotic therapy as appropriate.

Single subcutaneous or intravenous injection.

9. ADVICE ON CORRECT ADMINISTRATION

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The maximum number of broachings should be limited to 20.

10. WITHDRAWAL PERIOD

Meat and offal: 21 days
Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C
Keep the container in the outer carton in order to protect from light.
Once broached, use within 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Keep out of reach and sight of children

12. SPECIAL WARNING(S)

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.

As NSAID therapy can be accompanied by gastro-intestinal or renal impairment, adjunctive fluid therapy should be considered especially in the case of acute mastitis treatment.

In common with other NSAIDs, carprofen should not be administered simultaneously with another veterinary medicinal product of the NSAID or glucocorticoid class.

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.

However during clinical studies in cattle four different antibiotic classes were used, macrolides, tetracyclines, cephalosporins and potentiated penicllins without known interactions.

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.

Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies. Avoid skin contact with the product. Should this occur, wash the affected areas immediately.

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

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

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED

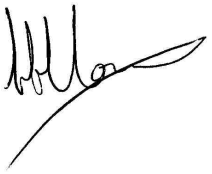
15. OTHER INFORMATION

For animal treatment only.

Rimadyl Cattle is available in a cardboard box containing one multidose amber glass (Type I) vial of either 50 ml, 100 ml or 250 ml capped with bromobutyl rubber stopper retained by an aluminium crimped seal.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Pfizer subsidiary in EU member states



Approved 03 December 2019