DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reproval 50mg/ml Solution for Injection for Dogs and Cats

Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 50mg Carprofen. Also contains Benzyl Alcohol (preservative) 10mg/ml and Sodium Formaldehyde Sulphoxylate (antioxidant) 2.5mg/ml.

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

20ml

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

See package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By intravenous or subcutaneous injection in the dog or intravenous administration in the cat.
See package leaflet.

8. SPECIAL WARNING(S), IF NECESSARY

Operator warnings – see package leaflet.

9. EXPIRY DATE

XX/XX/XXXX
Discard 28 days after first use.
Once broached use by: _____

10. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not refrigerate or freeze. Protect from light.

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

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

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

13. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

15. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4268
ManA 2000

16. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> number

<Supply category to be completed nationally>

Distributed by:

<Patent number to be completed nationally>

DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reproval 50mg/ml Solution for Injection for Dogs and Cats

Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 50mg Carprofen. Also contains Benzyl Alcohol (preservative) 10mg/ml and Sodium Formaldehyde Sulphoxylate (antioxidant) 2.5mg/ml.

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

1 x 20ml/5 x 20ml/6 x 20ml/10 x 20ml/12 x 20ml

5. TARGET SPECIES

For Dogs and Cats.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By intravenous or subcutaneous injection in the dog or intravenous administration in the cat.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not Applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings – see package leaflet.
Read the package leaflet before use.

10. EXPIRY DATE

XX/XX/XXXX

Discard 28 days after first use.
Once broached use by: _____
Do not use after the date shown after EXP on the top of this carton.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not refrigerate or freeze. Protect from light.

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal product 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

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

MARKETING AUTHORISATION HOLDER:

(EU)
Norbrook Laboratories (Ireland) Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> number

<Supply category to be completed nationally>

DISTRIBUTED BY:

<Patent number to be completed nationally>

DRAFT PACKAGE LEAFLET

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

MARKETING AUTHORISATION HOLDER:

(EU)
Norbrook Laboratories (Ireland) Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

MANUFACTURER RESPONSIBLE FOR BATCH RELEASE:

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reproval 50mg/ml Solution for Injection for Dogs and Cats

Carprofen

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

Each ml contains 50mg Carprofen. Also contains Benzyl Alcohol (preservative) 10mg/ml and Sodium Formaldehyde Sulphoxylate (antioxidant) 2.5mg/ml.

4. INDICATION(S)

Dogs: For the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery.

Cats: For the control of post operative pain following ovariohysterectomy and soft tissue surgery.

5. CONTRAINDICATIONS

Do not use after surgery which was associated with considerable blood loss.
Do not use in cats on repeated occasions.
Do not use in cats less than 5 months of age.
Do not use in dogs less than 10 weeks of age.
Do not use in animals suffering from cardiac, hepatic or renal disease or gastrointestinal problems, where there is a possibility of gastrointestinal ulceration or bleeding, or hypersensitivity to carprofen or any other NSAIDs or any excipients of this product.
As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.
See also Special Warnings.

6. ADVERSE REACTIONS

Typical undesirable effects associated with NSAIDs such as vomiting, soft faeces/diarrhea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.

Occasionally reactions at the injection site may be observed following subcutaneous injection.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and Cats.

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

In the dog the recommended dosage is 4mg/kg (1ml/12.5kg) bodyweight, by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia.
Clinical evidence in dogs suggests that only a single dose of carprofen is required in the first 24 hours of the initial dose, however if further analgesia is required post surgery within this 24 hour period, a single half-dose (2mg/kg) of carprofen may be given to dogs as necessary.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral therapy may be followed with Carprofen Tablets at 4 mg/kg/day for up to 5 days.
In the cat, the recommended dosage is 4mg/kg (0.24ml/3kg) bodyweight by intravenous injection as a single dose, best given pre-operatively at the time of induction of anaesthesia.

Precipitation may occur due to cold temperature. To re-dissolve warm and gently agitate the vial until precipitant is no longer evident.

9. ADVICE ON CORRECT ADMINISTRATION

In the cat, due to the longer half-life, and narrower therapeutic index, particular care should be taken not to exceed the recommended dose and the use of a graduated 1ml syringe is recommended to measure the dose accurately.
For peri-operative use it is recommended to administer the product at least 30 minutes before anaesthesia.

10. WITHDRAWAL PERIOD

Not Applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.
Do not use after the expiry date stated on the carton and the label.
Shelf life after first opening the container: 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 container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Keep out of the reach and sight of children.

12. SPECIAL WARNINGS

Special precautions for use in animals:
Do not exceed the recommended dose or duration of treatment especially in the cat.
Use in aged dogs and cats, may involve additional risk. If such use cannot be avoided, such animals may require a reduced dosage and careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.
Do not administer NSAIDs and glucocorticoids concurrently or within 24 hours of administration of the product
Carprofen is highly bound to plasma proteins and may compete with other highly bound drugs, which can lead to toxic effects.
Concurrent administration of potential nephrotoxic drugs should be avoided.
There is no specific antidote for carprofen overdosage, but general supportive therapy as applied to clinical overdosage with NSAIDs should be applied.
In the absence of compatibility studies this veterinary product cannot be mixed with other products.

Use during pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in dogs or cats during pregnancy or lactation.

Operator warnings

Care should be taken when handling the product to avoid accidental self-injection and skin contact. If skin contact occurs wash any product from the skin immediately. Wash hands after use.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

PACKAGE QUANTITIES:
The product is presented in packs of 1, 5, 6, 10 and 12 vials of 20mls.

Not all pack sizes may be marketed.

FOR ANIMAL TREATMENT ONLY

<Supply category to be completed nationally>

<Patent number to be completed nationally>

Approved: 03 June 2019