PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 5.0 % w/v Small Animal Solution for Injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains, Carprofen 5.0% w/v, Benzyl Alcohol 1.0% w/v (as preservative) and Sodium Formaldehyde Sulphoxylate 0.25% w/v (as antioxidant).

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs
Cats

6. INDICATION(S)

Carprieve 5%w/v Small Animal Solution for Injection is indicated in the dog for the control of post-operative pain and inflammation following orthopedic and soft tissue (including intra-ocular) surgery. In the cat it is indicated for the treatment of post-operative pain following surgery.

7. METHOD AND ROUTE(S) 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 peri-operatively; if further analgesia is required within this period, a single half-dose (2mg/kg) of carprofen may be given to dogs as necessary.

In the cat, the recommended dosage is 4mg/kg (0.24ml/3kg) bodyweight by subcutaneous or intravenous injection as a single dose, best given pre-operatively at the time of induction of anaesthesia. 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 1ml graduated syringe is recommended to measure the dose accurately.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer by intramuscular injection.
Do not exceed the recommended dose or duration of treatment.
Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.
Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or hypersensitivity to the product.
As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.
Do not use in cats less than 5 months of age. Use in dogs less than 6 weeks of age, or in aged cats and dogs, 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.
Concurrent administration of potential nephrotoxic drugs should be avoided.
In the absence of any specific studies in pregnant target animals such use is not indicated.
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.

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 immediately from the skin. Wash hands after use.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light.
Keep vial in outer carton
Following withdrawal of the first dose, use the product with 28 days.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

POM-V

To be supplied only by veterinary prescription.

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down,
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4229

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

PACKAGE QUANTITIES:

DISTRIBUTED BY:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 5.0% w/v Small Animal Solution for Injection.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains: Carprofen 5.0% w/v, Benzyl Alcohol 1.0% w/v (as preservative) and Sodium Formaldehyde Sulphoxylate 0.25% w/v (as antioxidant).

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

20 ml

4. PHARMACEUTICAL FORM

Solution for injection

5. ROUTE(S) OF ADMINISTRATION

See package leaflet

6. WITHDRAWAL PERIOD

Not applicable

6. OPERATOR WARNINGS

See package leaflet

7. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C. Protect from light. Keep vial in outer carton. Following withdrawal of the first dose, use the product within 28 days.

8. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

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

9. BATCH NUMBER

Bn.:
D.O.M.:

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

7. EXPIRY DATE

Exp.: dd/mm/yy

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.
POM-V To be supplied only on veterinary prescription

PACKAGE LEAFLET FOR:

Carprieve 5% w/v Small Animal Solution for Injection.

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down,
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 5% w/v Small Animal Solution for Injection.

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

Solution for Injection: Each ml contains, Carprofen 5.0% w/v, Benzyl Alcohol 1.0% w/v (as preservative) and Sodium Formaldehyde Sulphoxylate 0.25% w/v (as antioxidant).

4. INDICATION(S)

Carprieve 5 %w/v Small Animal Solution for Injection is indicated in the dog for the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery. In the cat it is indicated for the treatment of post-operative pain following surgery.

5. CONTRAINDICATIONS

Do not administer by intramuscular injection.
Do not exceed the recommended dose or duration of treatment.
Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.
For animal treatment only.

6. ADVERSE REACTIONS

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

"Typical undesirable effects associated with NSAIDs such as vomiting, soft faeces/diarrhoea, faecal occult blood, loss of appetite and lethargy have been reported in very rare instances.
These adverse reactions 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, idiosyncratic hepatic or gastro-intestinal tract adverse events.

Rarely reactions at the injection site may be observed following subcutaneous injection."

"The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)."

7. TARGET SPECIES

Dogs
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 administered by intravenous or subcutaneous injection, best given pre-operatively either at the time of premedication or induction of anaesthesia.
In the cat the recommended dosage is 4mg/kg (0.24ml/3kg) bodyweight administered as a single intravenous or subcutaneous injection, best given pre-operatively at the time of induction of anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

Clinical evidence in dogs suggests that only a single dose of carprofen is required in the first 24 hours peri-operatively; if further analgesia is required within this period, a single half-dose (2mg/kg) of carprofen may be given to dogs as necessary.

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 1ml graduated syringe is recommended to measure the dose accurately.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Protect from light.
Keep vial in outer carton.
Following withdrawal of the first dose, use the product with 28 days.

12. SPECIAL WARNING(S)

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

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or hypersensitivity to the product. As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.
Do not use in cats less than 5 months of age. Use in dogs less than 6 weeks of age, or in aged cats and dogs, 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.
Concurrent administration of potential nephrotoxic drugs should be avoided.
In the absence of any specific studies in pregnant target animals such use is not indicated.
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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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. The discard date should be written in the space provided

LEGAL CATEGORY:

POM-V

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES:

Carprieve 5%w/v Small Animal Solution for Injection is a Solution for Injection containing 50 mg carprofen per ml (5%w/v).
Carprieve 5%w/v Small Animal Solution for Injection is available in 20ml multidose amber glass (grade 1) vials, sealed with 20mm bromobutyl bungs and 20mm aluminium seals

Marketing Authorisation No:

Vm 02000/4229

DISTRIBUTED BY:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

Approved 28 October 2022