LABEL TEXT

[BLISTER]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50mg Flavoured Tablets for Dogs
Carprofen 50mg

2. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU) Norbrook Laboratories (Ireland) Limited
(UK) Norbrook Laboratories Limited

3. EXPIRY DATE

DOM:
EXP: dd/mm/yyyy

4. MANUFACTURER'S BATCH NUMBER

B.N.:

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

FOR ANIMAL TREATMENT ONLY

CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50mg Flavoured Tablets for Dogs
Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Carprofen	50mg

3. PHARMACEUTICAL FORM

Tablets
The tablets can be divided into equal parts.

4. PACKAGE SIZE

20, 100, 200, 500 tablets.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

D.O.M.:
Exp.: dd/mm/ yyyy
Shelf-life after first opening the immediate packaging: 24 hours.
Any divided tablet portions remaining after 24 hours should be discarded.

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.
Protect from light.
Do not store above 25 ºC
Divided tablets should be stored in the blister pack.

Due to the palatable nature of the tablets, store in a secure location. Severe adverse reactions may occur if large quantities are ingested. If you suspect your dog has consumed Carprieve 50mg Flavoured Tablets for Dogs above the labelled dose, please contact your veterinarian.

12. SPECIAL 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

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

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4304

17. MANUFACTURER'S BATCH NUMBER

BN:

INSERT TEXT

CARPRIEVE 50mg FLAVOURED TABLETS FOR DOGS

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) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Newry,
Co. Down, BT35 6JP
Northern Ireland

Manufacturer Responsible for Batch Release:
(EU)
Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Newry,
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50mg Flavoured Tablets for Dogs
Carprofen.

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

Each light brown tablet contains:
Carprofen 50 mg
The tablets can be divided into equal parts.

4. INDICATION(S)

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease in the dog.

The tablets also can be used in the management of post operative pain.

5. CONTRAINDICATIONS

Do not exceed the stated dose.

Do not use in cats.

Do not use in dogs suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of blood dyscrasia or hypersensitivity to the product.

Do not use in puppies less than 4 months.

Do not use in case of hypersensitivity to active substance or to any of the excipients.

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.

As with other NSAIDs there is a rare risk of renal or idiosyncratic hepatic adverse events.
If you notice any side effects or any other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

For oral administration. The tablets are palatable and willingly consumed by most dogs when offered. The tablets can be divided into equal halves.
2 to 4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral preoperative treatment may be followed with Carprofen tablets at 4mg/kg/day for up to 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision.

Do not exceed the stated dose.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store in a dry place.
Protect from light.
Do not store above 25 ºC
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after “EXP”.
Divided tablets should be stored in the blister pack.
Shelf-life after first opening the immediate packaging: 24 hours.
Any divided tablet portions remaining after 24 hours should be discarded.

Due to the palatable nature of the tablets, store in a secure location. Severe adverse reactions may occur if large quantities are ingested. If you suspect your dog has consumed Carprieve 50mg Flavoured Tablets for Dogs above the labelled dose, please contact your veterinarian.

12. SPECIAL WARNINGS

Special precautions for use in animals:

Use in aged dogs may involve additional risk. If such a use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive dog, 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.

Studies in laboratory species (rat and rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches. For breeding animals, do not use during reproduction period.

Carprofen is highly bound to plasma proteins and competes with other highly bound drugs, which can increase their respective toxic effects. Do not use this veterinary medicinal product concurrently with or within 24 hours of other NSAIDs or concurrently with glucocorticoids. Concurrent administration of potentially nephrotoxic drugs should be avoided.

Do not administer concurrently with anticoagulants.

There is no specific antidote for carprofen over dosage but general supportive therapy as applied to clinical over dosage with NSAIDs should be applied.

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

No signs of toxicity were observed when dogs were administered the product at levels up to 6 mg/kg twice daily for 8 days (3 times the maximum recommended dose rate of 4 mg/kg/day) and 6 mg/kg once daily for a further 7 days (1.5 times the maximum recommended dose rate

of 4 mg/kg/day). There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs, should be applied. Severe adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed tablets above the labelled dose, contact your veterinarian.

User Warnings:

In case of accidental ingestion seek medical advice and show the package leaflet or the label to the physician. Wash hands after handling product.

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

July 2019

15. OTHER INFORMATION

ManA 2000

UK Only

POM-V

To be supplied only on veterinary prescription.

Vm: 02000/4304

Distributed by:

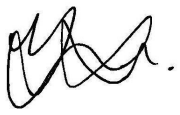
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Package Quantities:
Packs of 20, 100, 200 and 500 tablets.
Not all pack sizes may be marketed.

BN:
D.O.M:
Exp: dd/mm/yy

FOR ANIMAL TREATMENT ONLY

LOGO



Approved: 26 July 2019