

**LABEL TEXT**

**[BLISTER]**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Carprieve 100mg Flavoured Tablets for Dogs  
Carprofen 100mg

**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 100mg Flavoured Tablets for Dogs  
Carprofen

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:  
Carprofen            100mg

### 3. PHARMACEUTICAL FORM

Tablets  
The tablets can be divided into equal parts.

### 4. PACKAGE SIZE

20, 25, 100, 200 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 °C

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 100mg 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 02000/4305

**17. MANUFACTURER’S BATCH NUMBER**

BN:

**INSERT TEXT**

**CARPRIEVE 100mg 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 100mg Flavoured Tablets for Dogs  
Carprofen.

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

Each light brown tablet contains:

Carprofen 100 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 °C

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 100mg 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: 02000/4305

**Distributed by:**

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

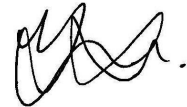
**Package Quantities:**

Packs of 20, 25, 100 and 200 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