

**LABEL TEXT – TUB EXPANDING LABEL  
PAGE 1**

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

**CARPROGESIC 50 mg TABLETS FOR DOGS, Carprofen**

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains: Carprofen 50 mg

**3. PHARMACEUTICAL FORM**

Tablet for oral administration.

**4. PACKAGE SIZE**

100/500 Tablets.

**5. TARGET SPECIES**

Dogs.

**6. INDICATION(S)**

Please refer to enclosed expanding label for further details.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read package leaflet before use.

For oral administration.

4mg 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. The daily dose may be reduced, subject to clinical response.

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.

To extend analgesic and anti-inflammatory cover post-operatively, parental pre-operative treatment with an injectable Carprofen product may be followed with Carprofen Tablets at 4mg/kg/day for 5 days.

**8. WITHDRAWAL PERIOD**

Not applicable.

**9. SPECIAL WARNING(S), IF NECESSARY**

Please refer to enclosed expanding label for further details.

**10. EXPIRY DATE**

XX/XX/XX

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Store in a dry place.

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

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

**[Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.] – UK Only**

**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**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm: 02000/4249

**17. MANUFACTURER'S BATCH NUMBER**

XXXXXXX

Man A: 2000

**Distributed by:**  
Pfizer Limited,  
Ramsgate Road,  
Sandwich,  
Kent,  
CT13 9NJ,  
UK

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

POM-V

To be supplied only on veterinary prescription

**LABEL TEXT – TUB EXPANDING LABEL  
PAGES 2 - 10**

**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  
Newry  
Co. Down,  
Northern Ireland, BT35 6JP

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

Carprogesic 50mg Tablets for Dogs

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

A white/off white circular tablet for oral administration containing 50 mg Carprofen.

**4. INDICATION(S)**

Reduction of inflammation and pain caused by musculo-skeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain.

**5. CONTRAINDICATIONS**

Do not use in cats.  
Do not use in pregnant or lactating bitches.  
Do not use in puppies less than 4 months of age.  
Do not use in case of hypersensitivity to active substance or to any of the excipients.  
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 a blood dyscrasia.

## **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.

If you notice any serious effects or 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.

4mg 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. The daily dose may be reduced, subject to clinical response.

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

To extend analgesic and anti-inflammatory cover post-operatively, parental pre-operative treatment with an injectable Carprofen product may be followed with Carprofen Tablets at 4mg/kg/day for 5 days.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Do not exceed the stated dose.

## **10. WITHDRAWAL PERIOD**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. Store in a dry place.  
Keep out of the reach and sight of children.  
Do not use after the expiry date which is stated on the label.

## **12. SPECIAL WARNINGS**

Use in aged dogs may involve additional risk.  
If such a use cannot be avoided, dogs may require careful clinical management.  
Avoid use in any dehydrated, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.  
Concurrent administration of potential nephrotoxic drugs should be avoided. 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 other NSAIDs and glucocorticoids 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.

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.

Doses up to three times the recommended dosage are reported to be without adverse effect in dogs. There is no specific antidote to carprofen but general supportive therapy as applied to clinical overdose with NSAIDs should be applied

### **User Warnings:**

In the event of accidental ingestion of the tablets, seek medical advice and show the doctor the package leaflet. Wash hands after handling the product.

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

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

**[Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.] – UK Only**

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

**LEGAL CATEGORY:**

POM-V

To be supplied only on veterinary prescription.

**PACKAGE QUANTITIES:**

100 x 50 mg tablets per tub or carton (containing 10 blister strips)

500 x 50 mg tablets per tub or carton (containing 5 x 10 blister strips)

Not all pack sizes may be marketed.

ManA 2000

Vm: 02000/4249

**DISTRIBUTED BY:**

Pfizer Limited,  
Ramsgate Road,  
Sandwich,  
Kent,  
CT13 9NJ,  
UK

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

**CARPROGESIC 50 mg TABLETS - BLISTER LABEL**

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

**CARPROGESIC 50 mg TABLETS FOR DOGS**

50 mg carprofen

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

**3. EXPIRY DATE**

XX/XX/XX

**4. BATCH NUMBER**

XXXX

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

**FOR ANIMAL TREATMENT ONLY**



## CARTON TEXT

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**CARPROGESIC 50 mg TABLETS FOR DOGS, CARPROFEN**

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A white/off white circular tablet for oral administration containing 50 mg Carprofen.

### 3. PHARMACEUTICAL FORM

Tablet for oral administration.

### 4. PACKAGE SIZE

100 Tablets/500 Tablets (5 packs of 10 blister strips containing 10 tablets per strip).

### 5. TARGET SPECIES

Dogs.

### 6. INDICATION(S)

Reduction of inflammation and pain caused by musculo-skeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain.

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

For oral administration.

4mg 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. The daily dose may be reduced, subject to clinical response.

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.

To extend analgesic and anti-inflammatory cover post-operatively, parental pre-operative treatment with an injectable Caerprofen product may be followed with Carprofen Tablets at 4mg/kg/day for 5 days.

## 8. WITHDRAWAL PERIOD

Not applicable.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not use in cats.

Do not use in pregnant or lactating bitches.

Do not use in puppies less than 4 months of age.

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

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 a blood dyscrasia.

Use in aged dogs may involve additional risk.

If such a use cannot be avoided, dogs may require careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.

Concurrent administration of potential nephrotoxic drugs should be avoided. 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 other NSAIDs and glucocorticoids 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.

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.

### **User Warnings**

In the event of accidental ingestion of the tablets, seek medical advice and show the doctor the package leaflet. Wash hands after handling the product.

## 10. EXPIRY DATE

XX/XX/XX

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place.

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

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

**[Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.] – UK Only**

**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**

Norbrook Laboratories Limited  
Station Works  
Newry  
Northern Ireland, BT35 6JP

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4249

**17. MANUFACTURER’S BATCH NUMBER**

XXXXXXXX

**Legal Category:** POM-V To be supplied only on veterinary prescription.

ManA 2000

**Distributed by:**  
Pfizer Limited,  
Ramsgate Road,  
Sandwich,  
Kent,  
CT13 9NJ,  
UK

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

**PACKAGE LEAFLET  
CARPROGESIC TABLETS FOR DOGS**

**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  
Newry  
Co. Down,  
Northern Ireland, BT35 6JP

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

Carprogesic 20mg Tablets for Dogs  
Carprogesic 50mg Tablets for Dogs

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

A white/off white circular tablet for oral administration. Carprogesic Tablets are available in two strengths with the following active composition:

20 mg Carprofen.  
50 mg Carprofen.

**4. INDICATION(S)**

Reduction of inflammation and pain caused by musculo-skeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain.

**5. CONTRAINDICATIONS**

Do not use in cats.

Do not use in pregnant or lactating bitches.

Do not use in puppies less than 4 months of age.

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

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 a blood dyscrasia.

## **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.

If you notice any serious effects or 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.

4mg 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. The daily dose may be reduced, subject to clinical response.

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

To extend analgesic and anti-inflammatory cover post-operatively, parental pre-operative treatment with an injectable Carprofen product may be followed with Carprofen Tablets at 4mg/kg/day for 5 days.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Do not exceed the stated dose.

**10. WITHDRAWAL PERIOD**

Not applicable.

**11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. Store in a dry place.  
Keep out of the reach and sight of children.  
Do not use after the expiry date which is stated on the label.

**12. SPECIAL WARNINGS**

Use in aged dogs may involve additional risk.  
If such a use cannot be avoided, dogs may require careful clinical management.  
Avoid use in any dehydrated, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.  
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Do not administer other NSAIDs and glucocorticoids 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.

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.

Doses up to three times the recommended dosage are reported to be without adverse effect in dogs. There is no specific antidote to carprofen but general supportive therapy as applied to clinical overdose with NSAIDs should be applied

**User Warnings:**

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**[Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.] – UK Only**

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

**LEGAL CATEGORY:**

POM-V
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 To be supplied only on veterinary prescription.

**PACKAGE QUANTITIES:**

100 x 20 mg tablets per tub or carton (containing 10 blister strips)  
100 x 50 mg tablets per tub or carton (containing 10 blister strips)  
500 x 50 mg tablets per tub or carton (containing 5 x 10 blister strips)

ManA 2000

Carprogesic 20mg Tablets for Dogs	Vm: 02000/4248
Carprogesic 50mg Tablets for Dogs	Vm: 02000/4249

Not all pack sizes may be marketed.

**DISTRIBUTED BY:**

Pfizer Limited,  
Ramsgate Road,  
Sandwich,  
Kent,  
CT13 9NJ,  
UK

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**