# LABEL TEXT – TUB BASE LABEL

**DOGS ONLY LOGO**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**NORODYL 50 mg TABLETS FOR DOGS**

## 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

Exp: 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

**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 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
BT35 6JP

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4266

## 17. MANUFACTURER'S BATCH NUMBER

XXXXXXX

Man A: 2000

**Distributed by:**
XL Vets
5 Atholl Crescent
Edinburgh
Midlothian
EH3 8EJ
Scotland

POM-V

To be supplied only on veterinary prescription

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT-** UK requirement only

# LABEL TEXT – TUB EXPANDING LABEL

**PAGE 1**

**DOGS ONLY LOGO**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**NORODYL 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. DOSAGE, 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

Exp: 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

**Dispose of any unused product and empty containers in accordance with guidance from your local waste 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 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: 02000/4266

## 17. MANUFACTURER'S BATCH NUMBER

XXXXXXX

Man A: 2000

**Distributed by:**
XL Vets
5 Atholl Crescent
Edinburgh
Midlothian
EH3 8EJ
Scotland

POM-V

To be supplied only on veterinary prescription

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

# LABEL TEXT – TUB EXPANDING LABEL
**PAGES 2 - 10**
**DOGS ONLY LOGO**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**NORODYL 50MG 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 x 50 mg tablets per tub.
500 x 50 mg tablets per tub.

## 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

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.

## 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.

**Operator 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

Exp: XX/XX/XX

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Store in a dry place.

## 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 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 REACH AND SIGHT OF CHILDREN"

**KEEP OUT OF THE REACH AND SIGHT OF CHILDREN**

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

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

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4266

## 17. MANUFACTURER'S BATCH NUMBER

XXXXXXXXX

**PACKAGE QUANTITIES:**

100 x 50 mg tablets per tub or carton (containing 10 x 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.

**LEGAL CATEGORY:** POM-V

To be supplied only on veterinary prescription

**DISTRIBUTED BY:**
XL Vets
5 Atholl Crescent
Edinburgh
Midlothian
EH3 8EJ
Scotland

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT-** UK requirement only

# NORODYL 50 mg TABLETS - BLISTER LABEL

**[NOTE: BLISTERS TO CONTAIN THE "DOG ONLY" SYMBOL]**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**NORODYL 50 mg TABLETS FOR DOGS**

50 mg carprofen

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

## 3. EXPIRY DATE

Exp: XX/XX/XX

## 4. BATCH NUMBER

XXXXXXXX

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

**FOR ANIMAL TREATMENT ONLY**

# CARTON TEXT

**[NOTE: CARTONS TO CONTAIN THE "DOG ONLY" SYMBOL]**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**NORODYL 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 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

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.

**Operator 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

Exp: 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

**Dispose of any unused product and empty containers in accordance with guidance from your local waste 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 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 02000/4266

## 17. MANUFACTURER'S BATCH NUMBER

XXXXXXXX

**Legal Category:** POM-V

To be supplied only on veterinary prescription

Man A: 2000

**Distributed by:**
XL Vets
5 Atholl Crescent
Edinburgh
Midlothian
EH3 8EJ
Scotland

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT-** UK requirement Only

# PACKAGE LEAFLET / INSERT TEXT
# NORODYL 20MG TABLETS FOR DOGS
# NORODYL 50MG 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, BT35 6JP
Northern Ireland

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodyl 20mg Tablets for Dogs (UK)
Norodyl 50mg Tablets for Dogs (UK)
Norocarp 20mg Tablets for Dogs (France)
Norocarp 50mg Tablets for Dogs (France)
Carprogesic 20mg Tablets for Dogs (Belgium, Germany, Luxembourg)
Carprogesic 50mg Tablets for Dogs (Belgium, Germany, Luxembourg)

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

A white/off white circular tablet for oral administration. Norodyl 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.

## 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.
Do not exceed the stated dose.

## 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 stated on the tub/carton.

## 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 overdosage with NSAIDs should be applied

**Operator 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

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

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

April 2007.

## 15. OTHER INFORMATION

**LEGAL CATEGORY:** POM-V

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)

Man A: 2000

| | |
|---|---|
| Norodyl 20mg Tablets for Dogs | Vm: 02000/4265 |
| Norodyl 50mg Tablets for Dogs | Vm: 02000/4266 |

Not all pack sizes may be marketed.

**DISTRIBUTED BY:**
XL Vets
5 Atholl Crescent
Edinburgh
Midlothian
EH3 8EJ
Scotland

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT-** UK requirement Only