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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORODYL 100 mg TABLETS FOR DOGS
Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Carprofen 100mg and Tartrazine (E102) 1.2 mg.

3. PHARMACEUTICAL FORM

Tablet for oral use.
The tablets can be divided into equal halves.

4. PACKAGE SIZE

Blister strips containing 10 tablets, in cartons containing either 10, 20, 30, 50, 60, 70, 100, 140, 180, 200, 250, 280, 300, 500 or 1000 tablets.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

In the dog:
Reduction of inflammation and pain caused by musculoskeletal 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 the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

dd/mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place. Protect from light.
Keep the blister in the outer carton.

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.

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 on veterinary prescription.

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

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

Ph: +44 (0) 28 302 64435
Fax: +44 (0) 28 302 61721
e-mail: enquiries@norbrook.co.uk

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4282
ManA 2000

17. MANUFACTURER'S BATCH NUMBER

Distributed by:

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

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LABEL TEXT – TUB EXPANDING LABEL
PAGE 1
DOGS ONLY LOGO

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORODYL 100 mg TABLETS FOR DOGS
Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Carprofen 100 mg and Tartrazine (E102) 1.2 mg.

3. PHARMACEUTICAL FORM

Tablet for oral use.
The tablets can be divided into equal halves.

4. PACKAGE SIZE

14, 30 or 100 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Read the expanding label before use.

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 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 parenteral pre-operative treatment with an injectable Carprofen product may be followed with Norodyl Tablets at 4mg/kg/day for up to 5 days.
Return any halved tablets to the original pack and use at the next administration. Any halved tablets remaining after the last administration of the product must be discarded.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the expanding label before use.

10. EXPIRY DATE

XX/XX/XX

11. SPECIAL STORAGE CONDITIONS

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

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.

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 on veterinary prescription.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4282

17. MANUFACTURER'S BATCH NUMBER

XXXXXXX

ManA: 2000

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

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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

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

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

Manufacturer responsible for batch release
Norbrook Laboratories Limited
105 Armagh Road
Newry
County Down
Northern Ireland, BT35 6PU

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodyl 100mg Tablets for Dogs
Carprofen.

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

A yellow circular tablet of 8 mm diameter, embossed "100" on one side and a single breakline on the other side.

Active Substance
Carprofen 100 mg

Excipients
Tartrazine (E102) 1.2 mg

The tablets can be divided into equal halves.

4. INDICATION(S)

In the dog:
Reduction of inflammation and pain caused by musculoskeletal 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 animals with known hypersensitivity to the 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/diarrhoea, 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 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 parenteral pre-operative treatment with an injectable Carprofen product may be followed with Norodyl Tablets at 4mg/kg/day for up to 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

Do not exceed the stated dose.
Return any halved tablets to the original pack and use at the next administration. Any halved tablets remaining after the last administration of the product must be discarded.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place. Protect from light.
Keep out of the sight and reach of children.
Do not use after the expiry date stated on the label after “EXP”

12. SPECIAL WARNINGS

Use in aged animals, may involve additional risk. If such use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.
Avoid use in any dehydrated, hypoproteinemic, 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.
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
Concurrent administration of potential nephrotoxic drugs should be avoided.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.
Do not exceed the stated dose. There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage 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.

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:

Norodyl Tablets are supplied in either:

Polypropylene Snap Secure Tubs containing 14, 30 or 100 tablets, sealed with a white Polyethylene Snap Secure Cap.

Aluminium-Aluminium blister strips with strips of 10 tablets in cartons containing 10, 20, 30, 50, 60, 70, 100, 140, 180, 200, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

ManA 2000

Vm: 02000/4282

DISTRIBUTED BY:

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

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LABEL TEXT – TUB BASELABEL
DOGS ONLY LOGO

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORODYL 100 mg TABLETS FOR DOGS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Carprofen 100 mg and Tartrazine (E102) 1.2 mg.

3. PHARMACEUTICAL FORM

Tablet for oral use.
The tablets can be divided into equal halves.

4. PACKAGE SIZE

14, 30 or 100 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Read the expanding label before use

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 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 parenteral pre-operative treatment with an injectable Carprofen product may be followed with Norodyl Tablets at 4mg/kg/day for up to 5 days.
Return any halved tablets to the original pack and use at the next administration. Any halved tablets remaining after the last administration of the product must be discarded.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Please refer to enclosed expanding label for further details.

10. EXPIRY DATE

dd/mm/yyyy

11. SPECIAL STORAGE CONDITIONS

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

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.

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 on veterinary prescription.

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

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

Ph: +44 (0) 28 302 64435
Fax: +44 (0) 28 302 61721
e-mail: enquiries@norbrook.co.uk

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4282
ManA: 2000

17. MANUFACTURER'S BATCH NUMBER

Distributed by:
Norbrook Laboratories (GB) Limited
The Green
Great Corby
Carlisle
Cumbria, CA4 8LR

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

NORODYL 100 mg TABLETS - BLISTER LABEL
[NOTE: BLISTERS TO CONTAIN THE "DOG ONLY" SYMBOL]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORODYL 100 mg TABLETS FOR DOGS
Each tablet contains: 100 mg carprofen

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

3. EXPIRY DATE

Exp: dd/mm/yyyy

4. BATCH NUMBER

XXXX

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

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

Manufacturer responsible for batch release
Norbrook Laboratories Limited
105 Armagh Road
Newry
County Down
Northern Ireland, BT35 6PU

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodyl 100mg Tablets for Dogs (UK & DK)
Paracarp 100mg Tablets for Dogs (Germany)
Norocarp 100mg Tablets for Dogs (all other CMS)
Carprofen.

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

A yellow circular tablet of 8 mm diameter, embossed "100" on one side and a single breakline on the other side.

Active Substance
Carprofen 100 mg

Excipients
Tartrazine (E102) 1.2 mg

The tablets can be divided into equal halves.

4. INDICATION(S)

In the dog:
Reduction of inflammation and pain caused by musculoskeletal 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 animals with known hypersensitivity to the 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/diarrhoea, 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 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 parenteral pre-operative treatment with an injectable Carprofen product may be followed with Norodyl Tablets at 4mg/kg/day for up to 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

Do not exceed the stated dose.
Return any halved tablets to the original pack and use at the next administration. Any halved tablets remaining after the last administration of the product must be discarded.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place. Protect from light.
Keep out of the sight and reach of children.
Do not use after the expiry date stated on the Blister and Carton after “EXP”

12. SPECIAL WARNINGS

Use in aged animals, may involve additional risk. If such use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.
Avoid use in any dehydrated, hypoproteinemic, 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.
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
Concurrent administration of potential nephrotoxic drugs should be avoided.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.
Do not exceed the stated dose. There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage 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.

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:

Norodyl Tablets are supplied in either:
Polypropylene Snap Secure Tubs containing 14, 30 or 100 tablets, sealed with a white Polyethylene Snap Secure Cap.

Aluminium-Aluminium blister strips with strips of 10 tablets in cartons containing 10, 20, 30, 50, 60, 70, 100, 140, 180, 200, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

ManA 2000

Vm: 02000/4282

DISTRIBUTED BY:

Norbrook Laboratories (GB) Limited
The Green
Great Corby
Carlisle
Cumbria, CA4 8LR

UK AUTHORISED VETERINARY MEDICINAL PRODUCT