PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> 100 / 500 TABLET CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

100 / 500 Tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease, in dogs.
Carprieve Tablets can also be used in the management of post-operative pain.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.
An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given in two equally divided doses. The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily dose after 7 days, subject to clinical response. See maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose	
Bodyweight (kg)	20 mg	50 mg
5.0	◖	-
10.0	●	-
12.5	-	◖
15.0	●◖	-
20.0	●●	-
25.0	-	●
37.5	-	●◖
50	-	●●

Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision. To extend analgesic cover post-operatively, parenteral administration of carprofen, may be followed with Carprieve Tablets.

8. WITHDRAWAL PERIOD

Nil

9. SPECIAL WARNING(S), IF NECESSARY

The use of Carprieve Tablets is contraindicated in the cat, and the inadvertent administration of oral carprofen tablets may induce life-threatening conditions in this species.
Do not exceed the stated dose.
Do not administer NSAIDs 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.
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 or hypersensitivity to the product.
Use in dogs less than 6 weeks of age, or 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, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.
In the absence of any specific studies in pregnant bitches, such use is not indicated.
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.

Operator Warnings
None

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC 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 *[Distribution category]*

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4221

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE> 100 / 250 TABLET BASE LABEL/ EXPANDING LABEL (PAGE 1)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Carprofen 50 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

100 / 500 Tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease, in dogs.
Carprieve Tablets can also be used in the management of post-operative pain.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.
An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given in two equally divided doses. The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily dose after 7 days, subject to clinical response. See maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose	
Bodyweight (kg)	20 mg	50 mg
5.0	◖	-
10.0	●	-
12.5	-	◖
15.0	●◖	-
20.0	●●	-
25.0	-	●
37.5	-	●◖
50	-	●●

Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision. To extend analgesic cover post-operatively, parenteral administration of carprofen, may be followed with Carprieve Tablets.

8. WITHDRAWAL PERIOD

Nil

9. SPECIAL WARNING(S), IF NECESSARY

Please refer to enclosed expanding label for further details

Operator Warnings
None

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC 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 *[Distribution category]*

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4221

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.

3. EXPIRY DATE

Exp: dd/mm/yy

4. BATCH NUMBER

Bn.:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For Animal Treatment Only.

PACKAGE LEAFLET FOR:

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

Carprieve 50 mg Tablets

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

A white/off white circular tablet for oral administration. Carprieve Tablets are available in two strengths with the following active composition:
20 mg Carprofen
50 mg Carprofen

4. INDICATION(S)

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease, in dogs.
Carprieve Tablets can also be used in the management of post-operative pain.

5. CONTRAINDICATIONS

The use of Carprieve Tablets is contraindicated in the cat, and the inadvertent administration of oral carprofen tablets may induce life-threatening conditions in this species.

6. ADVERSE REACTIONS

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

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given in two equally divided doses. The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily dose after 7 days, subject to clinical response. See maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose	
Bodyweight (kg)	20 mg	50 mg
5.0	◖	-
10.0	●	-
12.5	-	◖
15.0	●◖	-
20.0	●●	-
25.0	-	●
37.5	-	●◖
50	-	●●

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

To extend analgesic cover post-operatively, parenteral administration of carprofen, may be followed with Carprieve Tablets.

9. ADVICE ON CORRECT ADMINISTRATION

For oral administration to dogs.

10. WITHDRAWAL PERIOD

Nil

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25ºC.
Store in a dry place.
Protect from light

12. SPECIAL WARNINGS

Do not exceed the stated dose.
Do not administer NSAIDs 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.

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 or hypersensitivity to the product.
Use in dogs less than 6 weeks of age, or 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, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.
In the absence of any specific studies in pregnant bitches, such use is not indicated.
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.

Operator Warnings:
None

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

October 2022

15. OTHER INFORMATION

Carprieve Tablets 20 mg	Vm: 02000/4220
Carprieve Tablets 50 mg	Vm: 02000/4221

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)
Not all package sizes may be presented.

DISTRIBUTED BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

POM-V

To be supplied only by veterinary prescription

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, 100 / 500 TABLETS EXPANDING VIAL LABEL (PAGE 2-10)

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

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

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprieve 50 mg Tablets

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

A white/off white tablet for oral administration. Carprieve Tablets are available in two strengths with the following active composition:
20 mg Carprofen
50 mg Carprofen

4. PHARMACEUTICAL FORM

Tablet

5. PACKAGE SIZE

100 / 500 Tablets

6. INDICATION(S)

For analgesia and reduction of chronic inflammation, for example in degenerative joint disease, in dogs.
Carprieve Tablets can also be used in the management of post-operative pain.

7. CONTRAINDICATIONS

The use of Carprieve Tablets is contraindicated in the cat, and the inadvertent administration of oral carprofen tablets may induce life-threatening conditions in this species.

8. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

9. TARGET SPECIES

Dogs

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

An initial dose of 2 to 4 mg carprofen/kg bodyweight/day is recommended to be given in 2 equally divided doses. The dose may be reduced to 2 mg carprofen/kg bodyweight/day administered as a single daily dose after 7 days, subject to clinical response: see maintenance dose table below:

Maintenance Dose Table	Number of tablets per dose	
Bodyweight (kg)	20 mg	50 mg
5.0	◖	-
10.0	●	-
12.5	-	◖
15.0	●◖	-
20.0	●●	-
25.0	-	●
37.5	-	●◖
50	-	●●

10. ADVICE ON CORRECT ADMINISTRATION

For oral administration.
Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision. To extend analgesic cover

post-operatively, parenteral administration of carprofen, may be followed with Carprieve Tablets

12. WITHDRAWAL PERIOD

Not applicable

13. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25ºC.
Store in a dry place.
Protect from light

14. SPECIAL WARNING(S)

Do not exceed the stated dose.
Do not administer NSAIDs 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.
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 or hypersensitivity to the product.
Use in dogs less than 6 weeks of age, or 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, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.
In the absence of any specific studies in pregnant bitches, such use is not indicated.
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.

15. EXPIRY DATE

EXP:

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

Any unused product or waste material should be disposed of in accordance with national requirements.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

October 2022

18. 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 by veterinary prescription.

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4221

21. MANUFACTURER'S BATCH NUMBER

B.N.:

<22. OTHER INFORMATION>
PACKAGE QUANTITIES:

100 x 20 mg tablets per tub
100 x 50 mg tablets per tub
500 x 50 mg tablets per tub
Not all pack sizes may be marketed.

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

Approved 28 October 2022