

Veterinary Medicinal Product

Carprodyl Quadri 120 mg chewable tablets for dogs

PART I B

A – LABELLING

Pharmaceutical Form

Chewable tablet

Veterinary Medicinal Product

Carprodyl Quadri 120 mg chewable tablets for dogs

PART I B

A – LABELLING – “OUTER PACKAGE”

Pharmaceutical Form

Chewable tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprodyl Quadri 120 mg chewable tablets for dogs
Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One tablet contains:
Carprofen..... 120 mg

3. PHARMACEUTICAL FORM

Chewable tablet
Clover-shaped scored beige tablet
The tablet can be divided into four equal parts.

4. PACKAGE SIZE

12 tablets
120 tablets
240 tablets
480 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

Dosage schedule: Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C
Protect from light.
For shelf life of divided tablets: see package leaflet.

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

Disposable: read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - 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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4093

17. MANUFACTURER’S BATCH NUMBER

Batch:

Veterinary Medicinal Product

Carprodyl Quadri 120 mg chewable tablets for dogs

PART I B

A - LABELLING – BLISTER

Pharmaceutical Form

ChewableTablet

The aluminium foil is printed with the following mentions: refer to the points 1, 2 and 5.

The batch number and the expiry date (month/year) are printed on the blister pack (PVC side) refer to the point 3, 4.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprodyl Quadri 120 mg chewable tablets for dogs

Carprofen

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Logo

3. EXPIRY DATE

EXP: mm/yyyy

4. BATCH NUMBER

Batch

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Veterinary Medicinal Product

Carprodyl Quadri 120 mg chewable tablets for dogs

PART I B

B – PACKAGE LEAFLET

Pharmaceutical Form

Chewable tablet

PACKAGE LEAFLET

Carprodyl Quadri 120 mg chewable 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:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprodyl Quadri 120 mg chewable tablets for dogs

Carprofen

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

One tablet contains:

Carprofen.....120 mg

Clover-shaped scored beige tablet

The tablet can be divided into four equal parts.

4. INDICATION(S)

In the dog:

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 pregnant and lactating bitches.

Do not use in dogs aged less than 4 months in the absence of specific data.

Do not use in cats.

Do not use in dogs, suffering from cardiac, hepatic or renal disease, when there is a possibility of gastrointestinal ulceration or bleeding or where there is evidence of blood dyscrasia.

Do not use in case of hypersensitivity to the active substance, to other NSAID and to any of the excipients.

6. ADVERSE REACTIONS

Typical undesirable effects associated with NSAID, such as vomiting, soft faeces/diarrhea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions generally occur 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 NSAID 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.

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. The analgesic effect from each dose persists for at least 12 hours.

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 may be followed with carprofen tablets at 4 mg/kg/day for 5 days.

Do not exceed the stated dose.

Tablets can be broken as follows: Put the tablet on a flat surface, with its scored side facing the surface (convex face up).

With the tip of forefinger, exert a slight vertical pressure on the middle of the tablet to break it into halves. In order to obtain quarters, then exert a slight pressure on the middle of one half with forefinger.

Each chewable tablet can be quartered for accurate dosing according to the individual body weight of the animal.

Number of tablets per day	Dog weight (kg)	
$\frac{1}{4}$	≥ 7.5	< 14.4
$\frac{1}{2}$	≥ 14.5	< 20.9
$\frac{3}{4}$	≥ 21	< 29.9
1	≥ 30	< 37.4
$1 \frac{1}{4}$	≥ 37.5	< 44.9
$1 \frac{1}{2}$	≥ 45	< 52.4
$1 \frac{3}{4}$	≥ 52.5	< 59.9
2	≥ 60	< 70

9. **ADVICE ON CORRECT ADMINISTRATION**

The chewable tablets are flavoured and are accepted by dogs. The chewable tablets can be administered with or without food.

10. **WITHDRAWAL PERIOD**

Not applicable.

11. **SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 30°C

Protect from light.

Divided tablets should be stored in the blister pack. Any divided tablet portions remaining after 72 hours should be discarded.

Do not use the veterinary medicinal product after the expiry date stated on the blister and outer carton after EXP. The expiry date refers to the last day of that month.

12. **SPECIAL WARNING(S)**

Use during pregnancy and lactation

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.

Special precautions for use in animals

Use in dogs less than 6 weeks of age, or in aged dogs, may involve additional risk. If such a use cannot be avoided, 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.

NSAID can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

As with other NSAID, photodermatitis during treatment with carprofen has been observed in laboratory animals and in humans. These skin reactions have never been observed in dogs.

Do not administer other NSAID concurrently or within 24 hours of each other. Some NSAID may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Due to the good palatability of the tablet, they should be stored in a safe place out of the reach of animals. Intake of dose exceeding the recommended number of tablets may lead to severe adverse effects. If this is the case, seek veterinary assistance immediately.

Special precautions to be taken by the person administering the veterinary medicinal product to animals.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.

Wash hands after handling the product.

Interaction with other medicinal products and other forms of interaction

Carprofen is highly bound to plasma proteins and compete with other highly bound drugs, which can increase their respective toxic effects.

Do not use this veterinary medicinal drug concurrently with other NSAID or with glucocorticoids.

Concurrent administration of potentially nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.

Refers also to section "Special precautions for use"

Overdose

Bibliographic data report that carprofen is well tolerated in dogs at twice the recommended dosage for 42 days.

There is no specific antidote to carprofen but general supportive therapy as applied to clinical overdose with NSAIDs should be applied.

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

Any unused veterinary medicinal product or waste material 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

September 2022

15. OTHER INFORMATION

Pack sizes:

Cardboard box with 2 blisters of 6 tablets

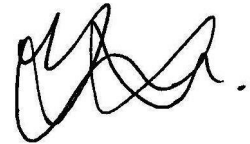
Cardboard box with 20 blisters of 6 tablets

Cardboard box with 40 blisters of 6 tablets
Cardboard box with 80 blisters of 6 tablets

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Local representative:

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 30 September 2022