**Veterinary Medicinal Product**

**Carprodyl Quadri 50 mg tablets for dogs**

**PART I B**

**A – LABELLING**

**Pharmaceutical Form**

**Tablet**

.

**Veterinary Medicinal Product**

**Carprodyl Quadri 50 mg tablets for dogs**

**PART I B**

**A – LABELLING – "OUTER PACKAGE"**

**Pharmaceutical Form**

**Tablet**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprodyl Quadri 50 mg tablets for dogs

Carprofen

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One tablet contains:
Carprofen.....50 mg

## 3. PHARMACEUTICAL FORM

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

## 4. PACKAGE SIZE

20 tablets
100 tablets
200 tablets
300 tablets
400 tablets
500 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: month/year

## 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

Disposal: 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 15052/4094

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

**Veterinary Medicinal Product**

**Carprodyl Quadri 50 mg tablets for dogs**

**PART I B**

**A - LABELLING – BLISTER**

**Pharmaceutical Form**

**Tablet**

*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 50 mg tablets for dogs

Carprofen

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Logo

## 3. EXPIRY DATE

EXP: month/year

## 4. BATCH NUMBER

Batch

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

For animal treatment only

**Veterinary Medicinal Product**

# Carprodyl Quadri 50 mg tablets for dogs

## PART I B

## B – PACKAGE LEAFLET

**Pharmaceutical Form**

**Tablet**

# PACKAGE LEAFLET

## Carprodyl Quadri 50 mg 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 50 mg tablets for dogs

Carprofen

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

One tablet contains:
Carprofen.....50 mg

## 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 NSAIDs and to any of the excipients.

## 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 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 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.
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 dependant 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.

The breakability method is the following: Put the tablet on a plain 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 in its width into halves. In order to obtain quarters, then exert a slight pressure on the middle of one half with forefinger to break it in its length.

The tablet is divisible and can be used as follows:

| Number of tablets per day | Dog weight (kg) |
|---|---|
| ¼ | > 3 - < 6 |
| ½ | ≥ 6 - < 9 |
| ¾ | ≥ 9 - < 12.5 |
| 1 | ≥ 12.5 - < 15.5 |
| 1 ¼ | ≥ 15.5 - < 18.5 |
| 1 ½ | ≥ 18.5 - < 21.5 |
| 1 ¾ | ≥ 21.5 - < 25 |
| 2 | ≥ 25 - < 28 |
| 2 ¼ | ≥ 28 - < 31 |
| 2 ½ | ≥ 31 - < 34 |
| 2 ¾ | ≥ 34 - < 37 |
| 3 | ≥ 37 - < 40 |
| 3 ¼ | ≥ 40 - < 43 |
| 3 ½ | ≥ 43 - < 45 |

## 9. ADVICE ON CORRECT ADMINISTRATION

The tablets are flavoured, and are accepted by dogs, but they may be administered directly in the mouth of the dog or added to food if necessary.

## 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. 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. Ask your veterinary surgeon for advice.

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.
As with other NSAIDs, 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 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.
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 NSAIDs or with glucocorticoids.
Concurrent administration of potentially nephrotoxic drugs (e.g. aminogylcoside antibiotics) should be avoided.

**Overdose**
Bibliographic data report that carprofen is well tolerated in dogs at twice the recommended dosage for 42 days.
Doses up to 3 times the recommended dose are reported to be without adverse effects.
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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

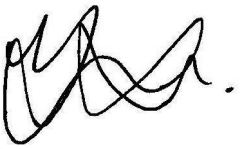
September 2022

## 15. OTHER INFORMATION

Pack sizes:
Cardboard box with 2 blisters of 10 tablets
Cardboard box with 10 blisters of 10 tablets
Cardboard box with 20 blisters of 10 tablets
Cardboard box with 30 blisters of 10 tablets
Cardboard box with 40 blisters of 10 tablets
Cardboard box with 50 blisters of 10 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:



Approved: 30 September 2022