ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprodyl Quadri 50 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
50 mg of Carprofen

3. PACKAGE SIZE

20 tablets
100 tablets
200 tablets
300 tablets
400 tablets
500 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/3026

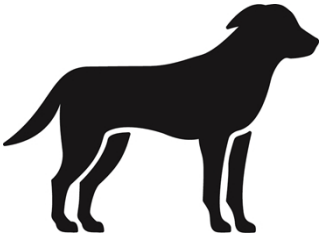
15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprodyl Quadri



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 mg of carprofen/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carprodyl Quadri 50 mg tablets for dogs

2. Composition

Each tablet contains:
Active substance: Carprofen .....50 mg

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

3. Target species

Dogs

4. Indications for use

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 (non-steroidal anti-inflammatory drugs) or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
Use 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.

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 or the label to the physician.
Wash hands after handling the veterinary medicinal product.

Pregnancy:
Laboratory studies in 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.. Do not use in pregnant bitches.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Do not use in dogs during lactation.

Fertility:
For breeding animals, do not use during reproduction period.

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.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Renal disorder [1] Hepatic disorder [1,3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vomiting[2], Soft stool[2] /Diarrhoea[2], Blood in faeces[2] Appetite loss[2], Lethargy[2]

[1]As with other NSAIDs

[2] Typical undesirable effects associated with NSAIDs, 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.

[3] Idiosyncratic effects

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.
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. To ensure a correct dosage, body weight should be determined as accurately as possible.

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 periods

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 which is stated on the blister and outer carton after “Exp”. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Vm 15052/3026

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH

United Kingdom Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

17. Other information

Gavin Hall
Approved: 01 December 2024