1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rycarfa 100 mg tablets for dogs (BE, DE, ES, FR, IE, IT, NL, PT, UK(NI))
Rycarfa vet 100 mg tablets for dogs (DK, FI)
Carprox vet. 100 mg tablets for dogs (AT)
Carprox 100 mg tablets for dogs (EL)
Carprofen Krka 100 mg tablets for dogs (NO)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:
Carprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ferric oxide red (E172)	3.04 mg
Ferric oxide black (E172)	1.90 mg
Lactose monohydrate	
Maize starch	
Povidone K30	
Sodium starch glycolate, type A	
Colloidal anhydrous silica	
Meat flavour 10022	
Talc	
Magnesium stearate	

Round, dark brown, marbled tablets with visible darker spots, one-side scored and bevel-edged.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in dogs less than 4 months of age.
Do not use in cases of 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.

3.4 Special warnings

Refer to Sections 3.3 and 3.5.

3.5 Special precautions for use

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 careful clinical management.
Avoid use in any dehydrated, 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.
See section 3.8.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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 product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Renal disorder. Hepatic disorder[1].
Undetermined frequency (cannot be estimated from the available data):	Vomiting[2], loose stool[2], diarrhoea[2], blood in faeces[2], appetite loss[2], lethargy [2].

[1] Idiosyncratic reaction.
[2] Transient. Generally, occur within the first treatment week and are in most cases disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, use of the veterinary medicinal 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rat and rabbit have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. Do not use in pregnant or lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs and glucocorticoids concurrently or within 24 hours of administration of the product. Carprofen is highly bound to plasma proteins and may compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided.

3.9 Administration routes and dosage

For oral use.

2 to 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 or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.
In order to adjust the dosage, the tablets can be divided into two equal parts.
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 preoperative treatment may be followed with Carprofen tablets at 4 mg/kg/day for up to 5 days.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Although studies investigating the safety of carprofen at overdose have been performed, no signs of toxicity appeared when dogs were treated with carprofen at levels up to 6 mg/kg twice daily for 7 days (3 times the recommended dose rate of 4 mg/kg) and 6 mg/kg once daily for a further 7 days. (1.5 times the recommended dose rate of 4 mg/kg).

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QM01AE91

4.2 Pharmacodynamics

Carprofen possesses anti-inflammatory, analgesic and antipyretic activity. Like most other NSAID's, carprofen is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade.
However, the inhibition of prostaglandin synthesis by carprofen is slight in relation to its anti-inflammatory and analgesic potency. The precise mode of action of carprofen is not clear.

Carprofen is a chiral drug with the S(+) enantiomer being more active than the R(-) enantiomer. There is no chiral inversion between the enantiomers *in-vivo*.

4.3 Pharmacokinetics

Carprofen is well absorbed after oral administration (>90%) and is highly protein bound. Peak plasma concentrations are achieved between 1 h and 3 h after administration.
Carprofen is characterized by a half-life of approximately 10 hours in dogs.
Carprofen is eliminated in dogs primarily by means of biotransformation in the liver, followed by rapid excretion of the resulting metabolites in feces (70-80%) and urine (10-20%). Some enterohepatic circulation has been detected.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Return any halved tablet to the opened blister and use within 24 hours.

5.3 Special precautions for storage

Store in the original package in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

Blister (OPA/Al/PVC-Al): 20, 50, 100 or 500 tablets (10 tablets/blister) in a box.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rycarfa 100 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: Carprofen 100 mg

3. PACKAGE SIZE

20 tablets
50 tablets
100 tablets
500 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Return any halved tablet to the opened blister and use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light and moisture.

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

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rycarfa

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

100 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rycarfa 100 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Carprofen 100 mg

Excipients:
Ferric oxide red (E172) 3.04 mg
Ferric oxide black (E172) 1.90 mg

Round, dark brown, marbled tablets with visible darker spots, one-side scored and bevel-edged.

3. Target species

Dogs.

4. Indications for use

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 dogs less than 4 months of age.
Do not use in cases of 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. 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 careful symptomatic management.
Avoid use in any dehydrated, 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.
See also “Interactions”.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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 product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rat and rabbit have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. Do not use in pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction:
Do not administer other NSAIDs and glucocorticoids concurrently or within 24 hours of administration of the product. Carprofen is highly bound to plasma proteins and may compete with other highly bound drugs, which can lead to toxic effects.
Concurrent administration of potential nephrotoxic drugs should be avoided.

Overdose:
Although studies investigating the safety of carprofen at overdose have been performed, no signs of toxicity appeared when dogs were treated with carprofen at levels up to 6 mg/kg twice daily for 7 days (3 times the recommended dose rate of 4 mg/kg) and 6 mg/kg once daily for a further 7 days. (1.5 times the recommended dose rate of 4 mg/kg).

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

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Renal disorder. Hepatic disorder[1].
Undetermined frequency (cannot be estimated from the available data):	Vomiting[2], loose stool[2], diarrhoea[2], blood in faeces[2], appetite loss[2], **lethargy** [2].

[1] Idiosyncratic reaction.
[2] Transient. Generally, occur within the first treatment week and are in most cases disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, use of the veterinary medicinal 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system: national system details

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

For oral use.
2 to 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 or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.

In order to adjust the dosage, the tablets can be divided into two equal parts.

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 preoperative treatment may be followed with Carprofen tablets at 4 mg/kg/day for up to 5 days.

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

9. Advice on correct administration

Not applicable.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package in order to protect from light and moisture.

Return any halved tablet to the opened blister and use within 24 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the 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 authorisation numbers and pack sizes

100 mg tablets are available in boxes of 20, 50, 100 and 500 tablets in blisters of 10 tablets.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>

<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
Tel: If applicable

Manufacturer responsible for batch release:
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

Local representatives and contact details to report suspected adverse events:

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

17. Other information