ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Orion 25 mg chewable tablets for dogs
Carprofen Orion 50 mg chewable tablets for dogs
Carprofen Orion 100 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

25 mg chewable tablet:
Carprofen 25 mg

50 mg chewable tablet:
Carprofen 50 mg

100 mg chewable tablet:
Carprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Povidone (K-30)
Lactose monohydrate
Cellulose, microcrystalline
Stearic acid
Silica, colloidal anhydrous
Sodium starch glycolate (type A)
Chicken liver powder, spray dried
Smoke flavour
Light brown sugar

The 25 mg chewable tablets are brown, round, biconvex, uncoated tablets debossed with “C 148” on one side and a score line on the other side. The tablets have a smoky, meaty aroma. The tablets can be divided into two equal doses.

The 50 mg chewable tablets are brown, round, biconvex, uncoated tablets debossed with “C 146” on one side and a score line on the other side. The tablets have a smoky, meaty aroma. The tablets can be divided into two equal doses.

The 100 mg chewable tablets are brown, square, flat, uncoated tablets debossed with “C” on one side and a double score line on both sides. The tablets have a smoky, meaty aroma. The tablets can be divided into four equal doses.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For alleviation of inflammation and pain in musculoskeletal and joint disorders and after surgical procedures.

3.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, gastrointestinal ulceration or bleeding, or suspected blood dyscrasia.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in cats, as the elimination time of carprofen is longer and therapeutic index narrower than in the dog.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The recommended doses must not be exceeded. The product should be used with particular caution in very young (less than 6 weeks of age) and in aged dogs.

Non-steroidal anti-inflammatory drugs (NSAID's) can cause inhibition of phagocytosis. Hence for the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Since the chewable tablets are flavoured, store the veterinary medicinal product in a secure location. Serious adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed more veterinary medicinal product than the recommended dose, please contact your veterinarian.

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

People with known hypersensitivity to carprofen should administer the veterinary medicinal product with caution.

Ingestion of the veterinary medicinal product may cause gastrointestinal signs, pain or nausea.

Care should be taken that children do not accidentally ingest the veterinary medicinal product. In order to avoid accidental ingestion, remove the tablet from the package immediately before administration.

In the event of accidental ingestion of the tablets, 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 Hepato-biliary disorder
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1], inappetence[1], blood in faeces[1] Lethargy[1]

[1] 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. In case of an adverse event use of the product should be discontinued and a veterinarian contacted.

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 also section "Contact details" of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Concomitant use of other NSAIDs or potent medicinal products that affect the kidneys should be avoided for 24 hours after a dose of the veterinary medicinal product. Carprofen is highly bound to plasma proteins and may therefore compete with other protein-bound medicines, which can lead to increased adverse events.

3.9 Administration routes and dosage

Oral use.

Days 1-6: 4 mg/kg once daily or divided into two doses.
Days 7-14: 2 mg/kg twice daily.
In maintenance therapy, 2 mg/kg/day is given once daily.
After intraoperative parenteral carprofen treatment, pain relief and treatment of inflammatory symptoms can be continued with tablets at a dose of 4 mg/kg body weight/day for 5 days.

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

Treatment is symptomatic.

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 is an NSAID belonging to the group of 2-arylpropionic acids. Carprofen possesses analgesic and anti-inflammatory activity.

The effect of carprofen is partly based on its inhibitory effect on the cyclo-oxygenase and lipoxygenase enzyme action. As a result, detrimental prostaglandins related to the inflammatory reaction are not produced. However, the inhibition of prostaglandin production by carprofen is so slight that it does not explain the full effect of the substance. At clinical doses in the dog, the inhibition of both cyclo-oxygenase enzyme and lipoxygenase enzyme action may be negligible or absent. Nonetheless, a good analgesic and anti-inflammatory effect is seen clinically. The reason for this is unknown.

Following repeated therapeutic dosing for 8 weeks, carprofen has been shown to have no detrimental effect on arthritic canine cartilage tissue. In addition, therapeutic concentrations of carprofen have been demonstrated *in vitro* to increase glycosaminoglycan synthesis (GAG) in chondrocytes isolated from canine arthritic cartilage tissue.

Stimulation of GAG synthesis will narrow the difference between the rate of degeneration and regeneration of cartilage matrix resulting in a slowing of the progression of cartilage loss.

4.3 Pharmacokinetics

Racemic carprofen is rapidly absorbed from the intestine. Bioavailability is > 90 %. The effect of food in the small intestine on absorption has not been studied. Maximum plasma concentration (C_{max}) is approximately 40 mcg/ml reached in 0.5-3 hours with approximate dose of 5 mg/kg. Carprofen is highly protein-bound, and therefore it has a small volume of distribution, V_d = 0.18 l/kg (calculated from intravenous dose). Clearance is slow, Cl = 3.8 ml/min x kg (result based on a single intravenous dose of 0.7 mg/kg).

Half-life ($t_{1/2}$) is approximately 8 hours with carprofen tablets.
Carprofen is excreted from the body by conjugation to glucuronides and subsequent oxidation. 70 % of the medicine is excreted in the faeces and 8-15 % in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

High-density polyethylene bottle fitted with a child resistant polypropylene closure.

Pack sizes:
Cardboard box containing 1 bottle of 20 chewable tablets of 25 mg.
Cardboard box containing 1 bottle of 60 chewable tablets of 25 mg.
Cardboard box containing 1 bottle of 60 chewable tablets of 50 mg.
Cardboard box containing 1 bottle of 10 chewable tablets of 100 mg.
Cardboard box containing 1 bottle of 20 chewable tablets of 100 mg.
Cardboard box containing 1 bottle of 60 chewable tablets of 100 mg.
Cardboard box containing 1 bottle of 180 chewable tablets of 100 mg.

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

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/328/001 (25 mg, 20 tablets)
EU/2/24/328/002 (25 mg, 60 tablets)
EU/2/24/328/003 (50 mg, 60 tablets)
EU/2/24/328/004 (100 mg, 10 tablets)
EU/2/24/328/005 (100 mg, 20 tablets)
EU/2/24/328/006 (100 mg, 60 tablets)
EU/2/24/328/007 (100 mg, 180 tablets)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/12/2024

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

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).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Orion 50 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Carprofen 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	10 mg
L-arginine	
Glycocholic acid	
Lecithin	
Sodium hydroxide	
Hydrochloric acid, concentrated	
Water for injections	

Clear pale yellow to yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each target species

Dog:
For perioperative alleviation of pain and inflammation especially in orthopaedic and soft tissue (including ocular) procedures.

Cat:
For perioperative alleviation of pain.

3.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, gastrointestinal ulceration or bleeding, or suspected blood dyscrasia.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. (See also section 3.5.)

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The recommended doses must not be exceeded. The product should be used with particular caution in very young (less than 6 weeks of age) and in aged animals.

Non-steroidal anti-inflammatory drugs (NSAID's) can cause inhibition of phagocytosis. Hence for the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. (See also section 3.3.)

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

People with known hypersensitivity to carprofen or benzyl alcohol should administer the veterinary medicinal product with caution.

This veterinary medicine may cause skin or eye irritation. Avoid contact with skin and eyes. Immediately wash the splashes with clean running water. If the irritation persists, seek medical advice and show the package leaflet or the label to the physician.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats

Rare (1 to 10 animals / 10 000 animals treated):	Injection site reaction[1] Renal disorder Hepato-biliary disorder Digestive tract disorders
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Vomiting[2], diarrhoea[2], inappetence[2], blood in faeces[2] Lethargy[2]

[1] After subcutaneous injection.

[2] 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. In case of an adverse event use of the product should be discontinued and a veterinarian contacted.

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 also section "Contact details" of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Concomitant use of other NSAIDs or potent medicinal products that affect the kidneys should be avoided for 24 hours after a dose of the veterinary medicinal product. Carprofen is highly bound to plasma proteins and may therefore compete with other protein-bound medicines, which can lead to increased adverse events.

3.9 Administration routes and dosage

Intravenous or subcutaneous use.

Dog:
A single dose of 4 mg/kg bodyweight.
Administration by intravenous or subcutaneous injection given either preoperatively with premedication or during induction of anaesthesia. The effect of the carprofen injection lasts for 24 hours. After 24 hours, analgesia in the dog can be continued with oral carprofen tablets at a dose of 4 mg/kg bodyweight/day for 5 days.

Cat:
A single dose of 4 mg/kg bodyweight.
Administration by subcutaneous or intravenous injection given preoperatively during induction of anaesthesia. Due to the longer half-life in cats and narrower therapeutic index particular care should be taken not to exceed or repeat the recommended dose.

The stopper of the vial may be punctured safely up to 25 times.

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

Treatment is symptomatic.

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 is an NSAID belonging to the group of 2-arylpropionic acids. Carprofen possesses analgesic and anti-inflammatory activity.

The effect of carprofen is partly based on its inhibitory effect on the cyclo-oxygenase and lipoxygenase enzyme action. As a result, detrimental prostaglandins related to the inflammatory reaction are not produced. However, the inhibition of prostaglandin production by carprofen is so slight that it does not explain the full effect of the substance. At clinical doses in the dog, the inhibition of both cyclo-oxygenase enzyme and lipoxygenase enzyme action may be negligible or absent. Nonetheless, a good analgesic and anti-inflammatory effect is seen clinically. The reason for this is unknown.

4.3 Pharmacokinetics

Dog
After intravenous administration the volume of distribution of carprofen is small, V_d = 0.18 l/kg in dogs. Clearance is slow, Cl = 3.8 ml/min x kg in dogs (based on a single intravenous injection dose 0.7 mg/kg). $T_{1/2}$ is 8.0 ± 1.2 h in dogs.
Carprofen is also absorbed subcutaneously. After subcutaneous injection the maximum plasma concentration 10.2 mcg/ml in dogs is reached within 4 hours.
Carprofen molecules are excreted from the body by conjugation to glucuronides and subsequent oxidation. 70 % of the medicine is excreted in the faeces and 8-15 % in the urine.

Cat
After a single dose (4.0 mg carprofen/kg) maximum plasma concentration (C_{max}) 26 mcg/ml is reached in 3.4 hours (t_{max}). Bioavailability is over 90 % and half-life ($t_{1/2}$) is approximately 20 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C-8 °C). Do not freeze.

5.4 Nature and composition of immediate packaging

Type I amber glass vial closed with grey coloured bromobutyl rubber stopper.

Pack sizes:
Cardboard box containing 5 vials of 20 ml.

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

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/328/008 (50 mg/ml, 5 vials)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/12/2024

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

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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Orion 25 mg chewable tablets
Carprofen Orion 50 mg chewable tablets
Carprofen Orion 100 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

1 chewable tablet:
25 mg carprofen
50 mg carprofen
100 mg carprofen

3. PACKAGE SIZE

10 tablets
20 tablets
60 tablets
180 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

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

Orion Corporation

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/328/001 (25 mg, 20 tablets)
EU/2/24/328/002 (25 mg, 60 tablets)
EU/2/24/328/003 (50 mg, 60 tablets)
EU/2/24/328/004 (100 mg, 10 tablets)
EU/2/24/328/005 (100 mg, 20 tablets)
EU/2/24/328/006 (100 mg, 60 tablets)
EU/2/24/328/007 (100 mg, 180 tablets)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Orion 25 mg chewable tablets
Carprofen Orion 50 mg chewable tablets
Carprofen Orion 100 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

1 chewable tablet:
25 mg carprofen
50 mg carprofen
100 mg carprofen

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Orion 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Carprofen 50 mg/ml

3. PACKAGE SIZE

5 x 20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous or subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze.

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

Orion Corporation

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/328/008 (50 mg/ml, 5 vials)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofen Orion 50 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Carprofen 50 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use by…

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carprofen Orion 25 mg chewable tablets for dogs

2. Composition

Active substance: carprofen 25 mg.

The 25 mg chewable tablets are brown, round, biconvex, uncoated tablets debossed with “C 148” on one side and a score line on the other side. The tablets have a smoky, meaty aroma. The tablets can be divided into two equal doses.

3. Target species

Dogs.

4. Indications for use

For alleviation of inflammation and pain in musculoskeletal and joint disorders and after surgical procedures.

5. Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, gastrointestinal ulceration or bleeding, or observed change in the blood count.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats, as the elimination time of carprofen is longer and therapeutic index narrower than in the dog.

6. Special warnings

Special precautions for safe use in the target species:
The recommended doses must not be exceeded.
Carprofen should be used with caution in very young (less than 6 weeks of age) and in very old dogs.

Non-steroidal anti-inflammatory drugs (NSAID’s) can cause inhibition of phagocytosis. Hence for the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Since the chewable tablets are flavoured, store the veterinary medicinal product in a secure location. Serious adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed the veterinary medicinal product more than the recommended dose, please contact your veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to carprofen should administer the veterinary medicinal product with caution.

Ingestion of the veterinary medicinal product may cause gastrointestinal signs, pain or nausea.

Care should be taken that children do not accidentally ingest the veterinary medicinal product. To prevent accidental ingestion, remove the tablet from the package immediately before giving it to the dog.

In the event of accidental ingestion of the tablets, 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. Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Concomitant use of other non-steroidal anti-inflammatory drugs (NSAIDs) or potent medicines that affect the kidneys should be avoided for 24 hours after a dose of this product.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):
Renal disorder Hepato-biliary disorder
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Vomiting[1], diarrhoea[1], lack of appetite[1], blood in the stool[1] Tiredness[1]

[1] 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. In case of an adverse event use of the product should be discontinued and a veterinarian contacted.

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 authorisation holder 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

Oral use.

Days 1-6: 4 mg/kg administered orally once daily or divided into two doses.
Days 7-14: 2 mg/kg twice daily.
In maintenance therapy, 2 mg/kg/day is given once daily.

After carprofen treatment administered as injection during an operation, pain relief and treatment of inflammatory symptoms can be continued with tablets at a dose of 4 mg/kg body weight/day for 5 days.

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.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle 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

EU/2/24/328/001-002

Cardboard box containing 1 bottle of 20 chewable tablets of 25 mg.
Cardboard box containing 1 bottle of 60 chewable tablets of 25 mg.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Local representatives and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien
V.M.D. nv
Hoge Mauw 900
2370 Arendonk, België
Tél/Tel: +32 14 67 20 51

Република България
Orion Corporation
Orionintie 1
FI-02200 Espoo
Тел: +358 10 4261

Česká republika
Orion Pharma s.r.o.
Na Strži 2102/61a,
Praha, 140 00
Tel: +420 227 027 263
orion@orionpharma.cz

Danmark
Orion Pharma A/S
Ørestads Boulevard 73,
2300 København S
Tlf: +45 86 14 00 00

Deutschland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Lietuva
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

Luxembourg/Luxemburg
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Magyarország
Orion Pharma Kft.
1139 Budapest, Pap Károly u. 4-6
Tel.: +36 1 2370603

Malta
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Nederland
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Eesti
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Leedu
Tel: +370 5 2769 499

Ελλάδα
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

España
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

France
Laboratoires Biové
3 Rue de Lorraine
62510 Arques
France
Tél: +33 3 21 98 21 21

Hrvatska
IRIS FARMACIJA d.o.o.
Bednjanska 12,
10000 Zagreb
Tel: +385 (0)91 2575 785

Ireland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Ísland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Italia
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Κύπρος
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Norge
Orion Pharma AS Animal Health
Postboks 4366 Nydalen,
N-0402 Oslo
Tlf: +47 4000 4190

Österreich
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Polska
Orion Pharma Poland Sp. z o.o.
ul. Fabryczna 5A,
00-446 Warszawa
Tel.: +48 22 8333177

Portugal
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

România
Orion Pharma Romania srl
B-dul T. Vladimirescu nr 22,
Bucureşti, 050883-RO
Tel: +40 31845 1646

Slovenija
IRIS d.o.o.
Cesta v Gorice 8
1000 Ljubljana
Tel: +386 (0)1 2006650

Slovenská republika
Orion Pharma s.r.o.
Na strži 2102/61a,
Praha, 140 00, ČR
Tel: +420 227 027 263
orion@orionpharma.sk

Suomi/Finland
ORION PHARMA Eläinlääkkeet
Orionintie 1
FI-02200 Espoo
Puh/Tel: 010 4261

Sverige
Orion Pharma AB, Animal Health
Golfvägen 2, SE-182 31 Danderyd
Tel: +46 8 623 64 40

Latvija
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

United Kingdom (Northern Ireland)
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carprofen Orion 50 mg chewable tablets for dogs

2. Composition

Active substance: carprofen 50 mg.

The 50 mg chewable tablets are brown, round, biconvex, uncoated tablets debossed with “C 146” on one side and a score line on the other side. The tablets have a smoky, meaty aroma. The tablets can be divided into two equal doses.

3. Target species

Dogs.

4. Indications for use

For alleviation of inflammation and pain in musculoskeletal and joint disorders and after surgical procedures.

5. Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, gastrointestinal ulceration or bleeding, or observed change in the blood count.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats, as the elimination time of carprofen is longer and therapeutic index narrower than in the dog.

6. Special warnings

Special precautions for safe use in the target species:
The recommended doses must not be exceeded.
Carprofen should be used with caution in very young (less than 6 weeks of age) and in very old dogs.

Non-steroidal anti-inflammatory drugs (NSAID’s) can cause inhibition of phagocytosis. Hence for the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Since the chewable tablets are flavoured, store the veterinary medicinal product in a secure location. Serious adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed the veterinary medicinal product more than the recommended dose, please contact your veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to carprofen should administer the veterinary medicinal product with caution.

Ingestion of the veterinary medicinal product may cause gastrointestinal signs, pain or nausea.

Care should be taken that children do not accidentally ingest the veterinary medicinal product. To prevent accidental ingestion, remove the tablet from the package immediately before giving it to the dog.

In the event of accidental ingestion of the tablets, 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. Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Concomitant use of other non-steroidal anti-inflammatory drugs (NSAIDs) or potent medicines that affect the kidneys should be avoided for 24 hours after a dose of this product.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):
Renal disorder Hepato-biliary disorder
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Vomiting[1], diarrhoea[1], lack of appetite[1], blood in the stool[1] Tiredness[1]

[1] 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. In case of an adverse event use of the product should be discontinued and a veterinarian contacted.

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 authorisation holder 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

Oral use.

Days 1-6: 4 mg/kg administered orally once daily or divided into two doses.
Days 7-14: 2 mg/kg twice daily.
In maintenance therapy, 2 mg/kg/day is given once daily.

After carprofen treatment administered as injection during an operation, pain relief and treatment of inflammatory symptoms can be continued with tablets at a dose of 4 mg/kg body weight/day for 5 days.

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.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle 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

EU/2/24/328/003

Cardboard box containing 1 bottle of 60 chewable tablets of 50 mg.

15. Date on which the package leaflet was last revised

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:

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Local representatives and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien
V.M.D. nv
Hoge Mauw 900
2370 Arendonk, België
Tél/Tel: +32 14 67 20 51

Република България
Orion Corporation
Orionintie 1
FI-02200 Espoo
Тел: +358 10 4261

Česká republika
Orion Pharma s.r.o.
Na Strži 2102/61a,
Praha, 140 00
Tel: +420 227 027 263
orion@orionpharma.cz

Danmark
Orion Pharma A/S
Ørestads Boulevard 73,
2300 København S
Tlf: +45 86 14 00 00

Deutschland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Lietuva
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

Luxembourg/Luxemburg
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Magyarország
Orion Pharma Kft.
1139 Budapest, Pap Károly u. 4-6
Tel.: +36 1 2370603

Malta
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Nederland
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Eesti
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Leedu
Tel: +370 5 2769 499

Ελλάδα
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

España
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

France
Laboratoires Biové
3 Rue de Lorraine
62510 Arques
France
Tél: +33 3 21 98 21 21

Hrvatska
IRIS FARMACIJA d.o.o.
Bednjanska 12,
10000 Zagreb
Tel: +385 (0)91 2575 785

Ireland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Ísland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Italia
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Κύπρος
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Norge
Orion Pharma AS Animal Health
Postboks 4366 Nydalen,
N-0402 Oslo
Tlf: +47 4000 4190

Österreich
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Polska
Orion Pharma Poland Sp. z o.o.
ul. Fabryczna 5A,
00-446 Warszawa
Tel.: +48 22 8333177

Portugal
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

România
Orion Pharma Romania srl
B-dul T. Vladimirescu nr 22,
Bucureşti, 050883-RO
Tel: +40 31845 1646

Slovenija
IRIS d.o.o.
Cesta v Gorice 8
1000 Ljubljana
Tel: +386 (0)1 2006650

Slovenská republika
Orion Pharma s.r.o.
Na strži 2102/61a,
Praha, 140 00, ČR
Tel: +420 227 027 263
orion@orionpharma.sk

Suomi/Finland
ORION PHARMA Eläinlääkkeet
Orionintie 1
FI-02200 Espoo
Puh/Tel: 010 4261

Sverige
Orion Pharma AB, Animal Health
Golfvägen 2, SE-182 31 Danderyd
Tel: +46 8 623 64 40

Latvija
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

United Kingdom (Northern Ireland)
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carprofen Orion 100 mg chewable tablets for dogs

2. Composition

Active substance: carprofen 100 mg.

The 100 mg chewable tablets are brown, square, flat, uncoated tablets debossed with “C” on one side and a double score line on both sides. The tablets have a smoky, meaty aroma. The tablets can be divided into four equal doses.

3. Target species

Dogs.

4. Indications for use

For alleviation of inflammation and pain in musculoskeletal and joint disorders and after surgical procedures.

5. Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, gastrointestinal ulceration or bleeding, or observed change in the blood count.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats, as the elimination time of carprofen is longer and therapeutic index narrower than in the dog.

6. Special warnings

Special precautions for safe use in the target species:
The recommended doses must not be exceeded.
Carprofen should be used with caution in very young (less than 6 weeks of age) and in very old dogs.

Non-steroidal anti-inflammatory drugs (NSAID’s) can cause inhibition of phagocytosis. Hence for the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Since the chewable tablets are flavoured, store the veterinary medicinal product in a secure location. Serious adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed the veterinary medicinal product more than the recommended dose, please contact your veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to carprofen should administer the veterinary medicinal product with caution.

Ingestion of the veterinary medicinal product may cause gastrointestinal signs, pain or nausea.

Care should be taken that children do not accidentally ingest the veterinary medicinal product. To prevent accidental ingestion, remove the tablet from the package immediately before giving it to the dog.

In the event of accidental ingestion of the tablets, 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. Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Concomitant use of other non-steroidal anti-inflammatory drugs (NSAIDs) or potent medicines that affect the kidneys should be avoided for 24 hours after a dose of this product.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):
Renal disorder Hepato-biliary disorder
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Vomiting[1], diarrhoea[1], lack of appetite[1], blood in the stool[1] Tiredness[1]

[1] 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. In case of an adverse event use of the product should be discontinued and a veterinarian contacted.

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 authorisation holder 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

Oral use.

Days 1-6: 4 mg/kg administered orally once daily or divided into two doses.
Days 7-14: 2 mg/kg twice daily.
In maintenance therapy, 2 mg/kg/day is given once daily.

After carprofen treatment administered as injection during an operation, pain relief and treatment of inflammatory symptoms can be continued with tablets at a dose of 4 mg/kg body weight/day for 5 days.

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.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle 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

EU/2/24/328/004-007

Cardboard box containing 1 bottle of 10 chewable tablets of 100 mg.
Cardboard box containing 1 bottle of 20 chewable tablets of 100 mg.
Cardboard box containing 1 bottle of 60 chewable tablets of 100 mg.
Cardboard box containing 1 bottle of 180 chewable tablets of 100 mg.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Local representatives and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien
V.M.D. nv
Hoge Mauw 900
2370 Arendonk, België
Tél/Tel: +32 14 67 20 51

Република България
Orion Corporation
Orionintie 1
FI-02200 Espoo
Тел: +358 10 4261

Česká republika
Orion Pharma s.r.o.
Na Strži 2102/61a,
Praha, 140 00
Tel: +420 227 027 263
orion@orionpharma.cz

Danmark
Orion Pharma A/S
Ørestads Boulevard 73,
2300 København S
Tlf: +45 86 14 00 00

Deutschland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Lietuva
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

Luxembourg/Luxemburg
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Magyarország
Orion Pharma Kft.
1139 Budapest, Pap Károly u. 4-6
Tel.: +36 1 2370603

Malta
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Nederland
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Eesti
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Leedu
Tel: +370 5 2769 499

Ελλάδα
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

España
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

France
Laboratoires Biové
3 Rue de Lorraine
62510 Arques
France
Tél: +33 3 21 98 21 21

Hrvatska
IRIS FARMACIJA d.o.o.
Bednjanska 12,
10000 Zagreb
Tel: +385 (0)91 2575 785

Ireland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Ísland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Italia
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Κύπρος
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Norge
Orion Pharma AS Animal Health
Postboks 4366 Nydalen,
N-0402 Oslo
Tlf: +47 4000 4190

Österreich
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Polska
Orion Pharma Poland Sp. z o.o.
ul. Fabryczna 5A,
00-446 Warszawa
Tel.: +48 22 8333177

Portugal
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

România
Orion Pharma Romania srl
B-dul T. Vladimirescu nr 22,
Bucureşti, 050883-RO
Tel: +40 31845 1646

Slovenija
IRIS d.o.o.
Cesta v Gorice 8
1000 Ljubljana
Tel: +386 (0)1 2006650

Slovenská republika
Orion Pharma s.r.o.
Na strži 2102/61a,
Praha, 140 00, ČR
Tel: +420 227 027 263
orion@orionpharma.sk

Suomi/Finland
ORION PHARMA Eläinlääkkeet
Orionintie 1
FI-02200 Espoo
Puh/Tel: 010 4261

Sverige
Orion Pharma AB, Animal Health
Golfvägen 2, SE-182 31 Danderyd
Tel: +46 8 623 64 40

Latvija
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

United Kingdom (Northern Ireland)
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Carprofen Orion 50 mg/ml solution for injection

2. Composition

Active substance:
Carprofen 50 mg/ml

Excipients:
Benzyl alcohol (E1519) 10 mg/ml

A clear, pale yellow to yellow solution.

3. Target species

Dogs and cats.

4. Indications for use

Dog:
Perioperative alleviation of pain and inflammation especially in orthopaedic and soft tissue (including ocular) procedures.

Cat:
Perioperative alleviation of pain.

5. Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, gastrointestinal ulceration or bleeding, or observed change in the blood count.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
The recommended doses must not be exceeded. Carprofen should be used with caution in very young (less than 6 weeks of age) and in very old animals.

Non-steroidal anti-inflammatory drugs (NSAID's) can cause inhibition of phagocytosis. Hence for the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to carprofen or benzyl alcohol should administer the veterinary medicinal product with caution.

This veterinary medicinal product may cause skin or eye irritation. Avoid contact with skin and eyes. Immediately wash the splashes with clean running water. If the irritation persists, seek medical advice and show the package leaflet or the label to the physician.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Concomitant use of other non-steroidal anti-inflammatory drugs (NSAIDs) or potent medicines that affect the kidneys should be avoided for 24 hours after a dose of this product.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10 000 animals treated):
Injection site reaction[1] Renal disorder Hepato-biliary disorder Digestive tract disorder
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Vomiting[2], diarrhoea[2], lack of appetite[2], blood in the stool[2] Tiredness[2]

[1] After a subcutaneous injection.

[2] 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. In case of an adverse event use of the product should be discontinued and a veterinarian contacted.

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 authorisation holder 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

Intravenous or subcutaneous use.

Dogs:
A single dose of 4 mg/kg bodyweight.
Administration by intravenous or subcutaneous injection given either preoperatively with premedication or during induction of anaesthesia. The effect of the carprofen injection lasts for 24 hours. After 24 hours, analgesia in the dog can be continued with oral carprofen tablets at a dose of 4 mg/kg bodyweight/day for 5 days.

Cats:
A single dose of 4 mg/kg bodyweight.
Administration by subcutaneous or intravenous injection given preoperatively during induction of anaesthesia. Due to the longer half-life in cats and narrower therapeutic index particular care should be taken not to exceed the recommended dose.

The stopper of the vial may be punctured safely up to 25 times.

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 a refrigerator (2 °C-8 °C). Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/24/328/008

Cardboard box containing 5 vials of 20 ml.

15. Date on which the package leaflet was last revised

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:

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Local representatives and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien
V.M.D. nv
Hoge Mauw 900
2370 Arendonk, België
Tél/Tel: +32 14 67 20 51

Република България
Orion Corporation
Orionintie 1
FI-02200 Espoo
Тел: +358 10 4261

Česká republika
Orion Pharma s.r.o.
Na Strži 2102/61a,
Praha, 140 00
Tel: +420 227 027 263
orion@orionpharma.cz

Lietuva
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

Luxembourg/Luxemburg
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Magyarország
Orion Pharma Kft.
1139 Budapest, Pap Károly u. 4-6
Tel.: +36 1 2370603

Danmark
Orion Pharma A/S
Ørestads Boulevard 73,
2300 København S
Tlf: +45 86 14 00 00

Deutschland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Eesti
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Leedu
Tel: +370 5 2769 499

Ελλάδα
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

España
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

France
Laboratoires Biové
3 Rue de Lorraine
62510 Arques
France
Tél: +33 3 21 98 21 21

Hrvatska
IRIS FARMACIJA d.o.o.
Bednjanska 12,
10000 Zagreb
Tel: +385 (0)91 2575 785

Ireland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Ísland
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Malta
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Nederland
V.M.D. nv
Hoge Mauw 900
2370 Arendonk
België
Tél/Tel: +32 14 67 20 51

Norge
Orion Pharma AS Animal Health
Postboks 4366 Nydalen,
N-0402 Oslo
Tlf: +47 4000 4190

Österreich
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Polska
Orion Pharma Poland Sp. z o.o.
ul. Fabryczna 5A,
00-446 Warszawa
Tel.: +48 22 8333177

Portugal
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

România
Orion Pharma Romania srl
B-dul T. Vladimirescu nr 22,
Bucureşti, 050883-RO
Tel: +40 31845 1646

Slovenija
IRIS d.o.o.
Cesta v Gorice 8
1000 Ljubljana
Tel: +386 (0)1 2006650

Slovenská republika
Orion Pharma s.r.o.
Na strži 2102/61a,
Praha, 140 00, ČR
Tel: +420 227 027 263
orion@orionpharma.sk

Italia
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Κύπρος
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261

Latvija
UAB „ORION PHARMA“
Ukmergės g. 126
LT-08100 Vilnius, Lietuva
Tel: +370 5 2769 499

Suomi/Finland
ORION PHARMA Eläinlääkkeet
Orionintie 1
FI-02200 Espoo
Puh/Tel: 010 4261

Sverige
Orion Pharma AB, Animal Health
Golfvägen 2, SE-182 31 Danderyd
Tel: +46 8 623 64 40

United Kingdom (Northern Ireland)
Orion Corporation
Orionintie 1
FI-02200 Espoo
Tel: + 358 10 4261