SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox 20 mg flavour tablets
Carprox 50 mg flavour tablets
Carprox 100 mg flavour tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Carprox 20 mg	carprofen	20 mg
Carprox 50 mg	carprofen	50 mg
Carprox 100 mg	carprofen	100 mg

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use

Reduction of inflammation and relief of pain associated with musculo-skeletal disorders (e.g., degenerative joint disease, tendinitis, muscle injuries), control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

4.3 Contraindications

It should not be used in dogs exhibiting previous hypersensitivity to carprofen. Do not use in animals suffering from gastrointestinal ulceration, haemorrhagic diathesis, impaired heart, liver and kidney function.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

Special precautions for use in animals

If side effect occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there may be a potential risk of increased renal toxicity.
Use in dogs less than 6 weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Although adverse effects appear to be uncommon with carprofen use in dogs, rarely inappetence, stomach irritation, vomiting, diarrhoea and gastrointestinal bleeding may occur. During target animal tolerance studies for Carprox tablets with 3 times the recommended daily dose administered for 15 days, no significant adverse reactions were reported.

4.7 Use during pregnancy, lactation or lay
The safety of the product has not been established during pregnancy and lactation. Therefore, the use of the product is not recommended in pregnant and lactating bitches.

4.8 Interaction with other medical products and other forms of interaction
Do not administer other NSAIDs concurrently or within 24 hours of each other concurrent administration of potential nephrotoxic or anticoagulant drugs should also be avoided.

4.9 Amounts to be administered and administration route
The recommended total daily dose is 4 mg carprofen/kg of body weight administered in two equally divided parts (2 mg carprofen/kg twice daily). Subject to clinical response, the dose may be reduced after 7 days to 2 mg carprofen/kg of body weight/day given as a single daily dose. For the control of postoperative pain administer the total daily dose approximately 2 hours before the procedure.
For oral use. The tablets can be given directly to the dog or disguised in food.

4.10 Overdose (symptoms, emergency procedures, antidotes)
Overdosing of carprofen may lead to lesions and haemorrhages in the alimentary tract, inappetence, diarrhoea and lethargy or rarely even to death of treated animals.

4.11 Withdrawal periods
Not applicable.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: non-steroidal anti-inflammatory drug (NSAID).
ATC Vetcode: QM01AE91

5.1 Pharmacodynamic properties
Carprofen is a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid derivative group with characteristic anti-inflammatory, analgesic and anti-pyretic properties. The mechanism of action of carprofen, like that of other NSAIDs, is believed to be associated with the inhibition of the prostaglandin synthesis enzymes (cyclo-oxygenases), however it has also been shown to inhibit several prostoglandins in inflammatory cell systems.

5.2. Pharmacokinetic properties
When administered orally to dogs, carprofen is approximately 90% bioavailable. Peak serum levels occur between 1-3 hours post dosing. The drug is highly bound to plasma proteins (99%) and has a low volume of distribution (0.12-0.22 l/kg). Carprofen is extensively metabolized in the liver primarily via glucuronidation and oxidative processes. About 70-80% of a dose is eliminated in the feces; 10-20% is eliminated in the urine. Elimination half-life of carprofen in the dog is approximately 8 to 12 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose monohydrate, cellulose, microcrystalline, sodium starch glycolate, magnesium stearate, dried yeast, liver flavour.

6.2 Incompatibilities
Not applicable.

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

6.4 Special precautions for storage
No special precautions for storage.

6.5 Nature and composition of the immediate packaging

Primary packaging: Aluminium/polyethylene heat sealed strips with 2 tablets per strip.
Secondary packaging: Paper carton.
Presentation:

Carprox 20 mg	10x2 tablettes/box; 50x2 tablettes/box
Carprox 50 mg	10x2 tablettes/box; 50x2 tablettes/box
Carprox 100 mg	10x2 tablettes/box; 50x2 tablettes/box

6.6 Special precautions for the disposal of unused medicinal products or waste materials derived from such medicinal products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

LAVET Pharmaceuticals Ltd.,
1161 Budapest
Ottó u. 14.
Hungary

8. MARKETING AUTHORIZATION NUMBER(S)

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALEM SUPPLY AND/OR USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

for all strenght

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox 20 mg flavour tablets
Carprox 50 mg flavour tablets
Carprox 100 mg flavour tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance
carprofen 20 mg/tablet
carprofen 50 mg/tablet
carprofen 100 mg/tablet

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

10x2 tablettes/box;
50x2 tablettes/box

5. TARGET SPECIES

Dog

6. INDICATION(S)

Reduction of inflammation and relief of pain associated with musculo-skeletal disorders (e.g., degenerative joint disease, tendinitis, muscle injuries), control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Expiry date: 00/0000

11. SPECIAL STORAGE CONDITIONS

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

LAVET Pharmaceuticals Ltd. 1161 Budapest, Ottó u. 14. Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot number

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprox 20 mg flavour tablets
Carprox 50 mg flavour tablets
Carprox 100 mg flavour tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lavet Kft.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:
Carprox 20 mg flavour tablets
Carprox 50 mg flavour tablets
Carprox 100 mg flavour tablets

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
LAVET Pharmaceuticals Ltd., 1161 Budapest, Ottó u. 14. Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT
Carprox 20 mg flavour tablets
Carprox 50 mg flavour tablets
Carprox 100 mg flavour tablets

3. STATEMENT OF THE ACTIVE SUBSTANCES

Each tablet contains:
Active substance:

Carprox 20 mg	carprofen	20 mg
Carprox 50 mg	carprofen	50 mg
Carprox 100 mg	carprofen	100 mg

4.INDICATION(S)
Reduction of inflammation and relief of pain associated with musculo-skeletal disorders (e.g., degenerative joint disease, tendinitis, muscle injuries), control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

5.CONTRAINDICATIONS
It should not be used in dogs exhibiting previous hypersensitivity to carprofen. Do not use in animals suffering from gastrointestinal ulceration, haemorrhogic diathesis, impaired heart, liver and kidney function.

6.ADVERSE REACTIONS
Although adverse effects appear to be uncommon with carprofen use in dogs, rarely inappetence stomach irritation, vomiting, diarrhoea and gastrointestinal bleeding may occur. If you notice any other side effects, please inform your veterinary surgeon. During target animal tolerance studies for Carprox tablets with 3 times the recommended daily dose administered for 15 days, no significant adverse reactions were reported.

7.TARGET SPECIES
Dogs.

8.DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
The recommended total daily dose is 4 mg/kg of body weight administered in two equally divided parts (2 mg/kg twice daily). Subject to clinical response, the dose may be reduced after 7 days to 2 mg carprofen/kg of body weight/day given as a single daily dose. For the control of postoperative pain administer the total daily dose approximately 2 hours before the procedure.

9.ADVICE ON CORRECT ADMINISTRATION
For oral use. The tablets can be given directly to the dog or disguised in food.

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

12. SPECIAL WARNING(S)
Use in dogs less than 6 weeks of age, or in aged animals, may involve additional risk. Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there may be a potential risk of increased renal toxicity. If such use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.
Special precautions for use in animals
If side effect occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Special precautions during pregnancy, lactation, lay
The safety of the product has not been established during pregnancy and lactation. Therefore, the use of the product is not recommended in pregnant and lactating bitches.
Interaction with other medicinal products and other forms of interaction
Do not administer other NSAIDs concurrently or within 24 hours of each other. Concurrent administration of potential nephrotoxic or anticoagulant drugs should also be avoided.
Overdose (symptoms, emergency procedures, antidotes)
Overdosing of carprofen may lead to lesions and haemorrhages in the alimentary tract, inappetence, diarrhoea and lethargy or rarely even to death of treated animals.

13.SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14.DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

15.OTHER INFORMATION
Primary packaging: Aluminium/polyethylene heat sealed strips with 2 tablets per strip.
Secondary packaging: paper box
Presentation:
Carprox 20 mg 10x2 tablettes/box; 50x2 tablettes/box
Carprox 50 mg 10x2 tablettes/box; 50x2 tablettes/box
Carprox 100 mg 10x2 tablettes/box; 50x2 tablettes/box
Not all pack sizes may be marketed.