SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Carprof 20 mg flavour tablets
Carprof 50 mg flavour tablets
Carprof 100 mg flavour tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

**Active substance:**
- Carprof 20 mg: carprofen 20 mg
- Carprof 50 mg: carprofen 50 mg
- Carprof 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 Carprof 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. PHARMAKOLOGICAL PROPERTIES
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 prostaglandins 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.
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 SALE/SUPPLY AND/OR USE
PARTICULARS TO APPEAR ON THE OUTER PACKAGE

for all strengths

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
<table>
<thead>
<tr>
<th>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>{NATURE/TYPE}</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carprof 20 mg flavour tablets</td>
</tr>
<tr>
<td>Carprof 50 mg flavour tablets</td>
</tr>
<tr>
<td>Carprof 100 mg flavour tablets</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. NAME OF THE MARKETING AUTHORISATION HOLDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lavet Kft.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. EXPIRY DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXP {month/year}</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. BATCH NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot {number}</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. THE WORDS “FOR ANIMAL TREATMENT ONLY”</th>
</tr>
</thead>
<tbody>
<tr>
<td>For animal treatment only.</td>
</tr>
</tbody>
</table>
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, haemorrhagic 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.