<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{Label, tablet container large}
{Label, Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolocarp flavour, 100 mg, chewable tablets for dogs
Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each chewable tablet contains:

Active substance:
Carprofen 100 mg

Excipients:
Liver flavour liquid 5 mg
Special dry flavour vegetarian 50 mg

3. PHARMACEUTICAL FORM

Chewable Tablet

4. PACKAGE SIZES

20 Tablets
100 Tablets

5. TARGET SPECIES

Dog

6. INDICATION(S)

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

EXP {month/year}
Shelf-life after first opening the tablet container: 1 year
Shelf-life of halved tablets: 48 hours
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Store in a dry place. Keep the tablet container tightly closed.

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

[Not requested on the immediate label]
Disposal: read package leaflet

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4018

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PACKAGE LEAFLET FOR:

Dolocarp flavour, 100 mg, chewable tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolocarp flavour, 100 mg, chewable tablets for dogs
Carprofen

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each chewable tablet contains:

Active substance:
Carprofen 100 mg

Excipients:
Liver flavour liquid 5 mg
Special dry flavour vegetarian 50 mg

Beige-brown tablets with a break-line.

4. INDICATION(S)

Dog:
Reduction of inflammation and pain caused by acute and chronic musculoskeletal disorders (e.g. osteoarthritis). 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 cases of hypersensitivity to active substance, to other NSAIDs and to any of the excipients.
Do not use in animals suffering from a cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or tendency to bleeding or where there is evidence of a blood dyscrasia.

6. ADVERSE REACTIONS

Typical undesirable effects associated with NSAIDs, such as vomiting, soft faeces/diarrhoea, faecal occult blood (visible black discolouration of the faeces), kidney dysfunction (increased thirst, increased or reduced urine volume) loss of appetite and lethargy have been reported. These adverse reactions occur generally 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. If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought. Temporary increase in ALT values is possible.
Very occasionally, cases of liver damage and liver dysfunction can occur.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Chewable tablet for oral use. The stated dose should not be increased.
Administer the dose of 4.0 mg per kg body weight once daily. In cases of long term treatment the initial dose may, subject to clinical response, be reduced to 2 mg per kg body weight once daily. Most dogs will voluntarily ingest Dolocarp chewable tablets.
The treatment period depends on the clinical development of the disease. Long-term treatment should only be performed under veterinary supervision.
The tablets can be broken along the breakline.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a dry place.

Keep the tablet container tightly closed.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf-life after first opening the tablet container:	1 year
Shelf life of halved tablets:	48 hours

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species
None.

Special precautions for use in animals
Use in dogs less than 6 weeks of age or in aged dogs may involve additional risk. If such use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.

Due to the good palatability of the chewable tablet, the tablets must be kept in a safe place for animals. Intake of doses exceeding the recommended number of chewable tablets may lead to severe adverse effects. If this is the case, seek veterinary assistance immediately.
Avoid use in any dehydrated, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.
Do not administer other NSAIDs and glucocorticoids concurrently or within 24 hours of each other.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Exposure to intense light during treatment may lead to photodermatitis in animals with low skin pigmentation. Such adverse reactions with carprofen have occurred in laboratory animals and humans. Although skin reactions of this kind have not yet been observed in dogs, they cannot be ruled out at present.

User Warnings

Carprofen may rarely cause a photosensitive skin allergy in some people. Avoid skin contact with the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
Wash hands after handling the product.

Use during pregnancy, lactation or lay
Studies in laboratory species (rat and rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction
Do not administer NSAIDs and glucocorticoids concurrently or within 24 hours of each other. Concurrent administration of potential nephrotoxic drugs should be avoided. Refers also to section “Special precautions for use in animals”.
Carprofen has a high affinity for plasma protein (99% binding). For this reason, it should not be administered simultaneously with other substances which also demonstrate a high degree of plasma protein binding. In the case of pre-treatment with steroidal or non-steroidal anti-inflammatories, there must be a treatment-free period as the severity of possible adverse effects could otherwise be intensified.

Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of the typical side effects of nonsteroidal anti-inflammatory drugs such as gastrointestinal disorders (anorexia, vomiting, diarrhoea, ulceration), gastrointestinal bleeding (indicated by a blackening of the faeces) or signs of kidney dysfunction (increased thirst, increased or reduced urine volume), treatment should be discontinued immediately and the advice of a veterinarian sought.

Although studies investigating the safety of the product 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 4mg/kg) and 6mg/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.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{MM/YYYY}

15. OTHER INFORMATION

White tablet container made of high-density polyethylene with a childproof seal in a cardboard box. The product is closed with a white polypropylene cap with or without a desiccant.

Pack sizes: 20 and 100 tablets.
Not all pack sizes may be marketed.

Advice how to open the child-proof container: Push down and turn to open. Close tightly.

To be supplied only on veterinary prescription.

Approved 23 March 2017