PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofelican 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Carprofen 50 mg/ml
Benzyl alcohol (E1519) 15.0 mg/ml

3. PACKAGE SIZE

20 ml
5 x 20 ml
10 x 20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intravenous and subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp: <month/year>
Shelf life after first opening the vial: 28 days.
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the vial in the outer carton in order to protect from light.

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/5007

15. BATCH NUMBER

Lot <number>

16. SPECIAL WARNING(S), IF NECESSARY

Avoid skin contact, if occurs, immediately wash with water.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {VIAL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofelican 50 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Carprofen 50.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp: <month/year>
Shelf life after first opening the vial: 28 days.
Once broached, use by:

5. ROUTE(S) OF ADMINISTRATION

Dogs, Cats: IV, SC

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofelican 50 mg/ml solution for injection for dogs and cats

2. COMPOSITION

Each ml contains:

Active substance:
Carprofen: 50.0 mg

Excipients:
Benzyl alcohol (E1519) 15.0 mg

Clear brownish-yellow solution.

3. TARGET SPECIES

Dogs and cats.

4. INDICATIONS FOR USE

Dogs: for the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery.

Cats: for the control of post-operative pain following surgery.

5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal disease or gastrointestinal problems, where there is a possibility of gastro-intestinal ulceration or bleeding.
Do not use in cases of hypersensitivity to the active substance or any other NSAIDs (non-steroidal anti-inflammatory drugs) or any excipients of this product.
Do not administer by intramuscular injection.
Do not use after surgery which was associated with considerable blood loss.
Do not use in cats on repeated occasions.
Do not use in cats less than 5 months of age.
Do not use in dogs less than 10 weeks of age.
Do not use in dogs or cats during pregnancy or lactation.

6. SPECIAL WARNINGS

Special precautions for use in animals
Do not exceed the recommended dose or duration of treatment.
Due to the longer half-life in cats and narrower therapeutic index, particular care should be taken not to exceed the recommended dose and the dose should not be repeated.

Use in aged dogs and cats, may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity.

NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, appropriate concurrent antimicrobial therapy should be instigated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to carprofen should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.
Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies.
Avoid contact with skin and eyes. Wash off any splashes immediately with clean, running water.
Seek medical attention if irritation persists.

Use during pregnancy, lactation or lay
Pregnancy:
Laboratory studies in laboratory animals (rat, 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. Do not use in dogs or cats during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Do not use in dogs or cats during lactation.

Interaction with other medicinal products and other forms of interaction
Carprofen should not be administered concurrently, or within 24 hours of another NSAID, or in conjunction with glucocorticosteroids. Carprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects. Hence, concurrent administration with potentially nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes), if necessary
There is no specific antidote for carprofen overdosage. General symptomatic treatment, as is usual for clinical overdosage with NSAIDs, should be applied.

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[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports)	Vomiting[bc], diarrhoea[bc], loose stool[bc], blood in faeces[bc] appetite loss[bc], lethargy[b]
Undetermined frequency (cannot be estimated from the available data)	Vomiting[bd], diarrhoea[bd], loose stool[bd], blood in faeces[bd] appetite loss[bd]

[a] following subcutaneous injection
[b] most cases are transient and disappear following termination of the treatment but in very rare cases may be serious or fatal
[c] In Dogs only.
[d] In Cats only.

As with other NSAIDs there is a risk of rare renal, idiosyncratic hepatic or gastro-intestinal tract adverse events.

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

Dogs: For intravenous and subcutaneous use.

4 mg/kg (1 ml/12.5 kg) bodyweight, by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia. To extend analgesic and anti-inflammatory cover post-operatively, parenteral therapy may be followed with Carprofen tablets at 4 mg/kg/day for up to 5 days.

Cats: For intravenous and subcutaneous use.
4 mg/kg (0.08 ml/1.0 kg) bodyweight by intravenous or subcutaneous injection, best given pre-operatively, either at the time of premedication or induction of anaesthesia. The use of a 1 ml graduated syringe is recommended to measure the dose accurately (see also section 12). The parenteral therapy may not be followed with Carprofen tablets.

9. ADVICE ON CORRECT ADMINISTRATION

The weight of treated animals should be accurately determined before administration.
The stopper should not be punctured more than 20 times.

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.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the vial: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

For animal treatment only - to be supplied only on veterinary prescription.
POM-V

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41821/5007

Packaging:
Injection vial containing 20 ml.

Pack sizes:
Multi-packs of 5 x 20 ml and 10 x 20 ml.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

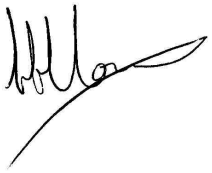
Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

17. OTHER INFORMATION

POM-V

For animal treatment only



Approved 09 January 2024