A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Carprofen 50 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

20 ml
5 x 20 ml
10 x 20 ml

5. TARGET SPECIES

Dogs, cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous use, subcutaneous use

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Avoid skin contact, if occurs, immediately wash with water.
Read the package leaflet before use.

10. EXPIRY DATE

EXP: <month/year>
<National issue PL: Termin ważności (EXP)>
Shelf life after first opening the bottle: 28 days.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

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

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.
<National issue: POM>

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 41821/4003

17. MANUFACTURER'S BATCH NUMBER

Batch: <number>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carprofelican 50 mg/ml injection for dogs and cats
Carprofen

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Carprofen 50 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs, Cats: IV, SC

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch: <number>

7. EXPIRY DATE

EXP: <month/year>
Once broached, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

<National issue: POM>
For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each ml contains:

Active substance:
Carprofen: 50.0 mg

Excipients:
Benzyl alcohol (E1519) 15.0 mg

Clear brownish-yellow solution.

4. INDICATION(S)

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

Cat: 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 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. ADVERSE REACTIONS

Typical undesirable effects associated with NSAIDs such as vomiting, soft faeces/diarrhoea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions 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.
As with other NSAIDs there is a risk of rare renal, idiosyncratic hepatic or gastro-intestinal tract adverse events.
Rarely reactions at the injection site may be observed following subcutaneous injection.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs, cats.

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

Dog: intravenous or 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.

Cat: intravenous or 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 PERIOD

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 bottle 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.
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 WARNING(S)

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 animal, 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 photosensitizing 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

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 and lactation. Do not use in dogs or cats during pregnancy or 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.

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. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<DD month YYYY>

15. OTHER INFORMATION

Injection bottle containing 20 ml.
Multi-packs of 5 x 20 ml and 10 x 20 ml.
Not all pack sizes may be marketed.

Approved: 07 November 2018