PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profexx 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carprofen	50 mg/ml
Benzyl alcohol	10 mg/ml
Ethanol 96%	0.104 ml/ml

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

SC, IV

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 21 days
Milk: zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

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 animals 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

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5027

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE { Glass vial 100 ml and 250 ml }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profexx 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Carprofen	50 mg/ml
Benzyl alcohol	10 mg/ml
Ethanol 96%	0.104 ml/ml

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

SC, IV

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 21 days
Milk: zero hours

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS { Glass vial 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profexx

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

50 mg/ml carprofen

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

5. ROUTE(S) OF ADMINISTRATION

SC, IV

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animals treatment only

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profexx 50 mg/ml solution for injection for cattle

2. COMPOSITION

Each ml contains:
Active substance:

Carprofen	50 mg

Excipients:

Benzyl alcohol	10 mg
Ethanol 96%	0.104 ml

Clear, colourless to yellow coloured solution for injection.

3. TARGET SPECIES

Cattle

4. INDICATIONS FOR USE

An adjunct to antimicrobial therapy to reduce clinical signs in acute infectious respiratory disease and acute mastitis in cattle.

5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal impairment.
Do not use in animals suffering from gastro-intestinal ulceration or bleeding.
Do not use where there is evidence of a blood dyscrasia.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNING(S)

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided Do not exceed the stated dose or the duration of treatment.
Do not administer other non-steroidal anti-inflammatory drugs (NSAID's) concurrently or within 24 hours of each other.
As NSAID therapy can be accompanied by gastro-intestinal or renal impairment, adjunctive fluid therapy should be considered especially in the case of acute mastitis treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Carprofen, in common with other NSAIDs, has been shown to exhibit photosensitising potential in laboratory studies. Benzyl alcohol and macrogol may cause hypersensitivity (allergic) reactions. People with known (hyper)sensitivity to carprofen, NSAIDs, benzyl alcohol or macrogol should administer the veterinary medicinal product with caution. Avoid contact with skin. Wash off any splashes immediately with clean, running water. Seek medical attention if irritation persists. Take care to avoid self-injection. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
In common with other NSAIDs, carprofen should not be administered simultaneously with another veterinary medicinal product of the NSAID or glucocorticoid class. NSAID's are highly bound to plasma proteins and may compete with other highly bound drugs, such that concomitant administration may result in toxic effects. However during clinical studies in cattle four different antibiotic classes were used, macrolides, tetracyclines, cephalosporins and potentiated penicillins without known interactions.

Overdose:
In clinical studies, no adverse signs were reported after intravenous and subcutaneous administration of up to 5 times the recommended dose.
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAID's, 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

Undetermined frequency (cannot be estimated from the available data)	Injection site reaction*

* transient local reaction

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, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

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

For subcutaneous and intravenous use.
Single injection at a dosage of 1.4 mg carprofen/ kg body weight (corresponding to 1 ml of the veterinary medicinal product/35 kg bodyweight) in combination with antibiotic therapy, as appropriate.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and offal: 21 days
Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store the vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

To be supplied only on veterinary prescription POM-V

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36408/5027

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

17. OTHER INFORMATION

Approved 27 March 2024