

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelaprofen 100 mg/ml, solution for injection for cattle, horses and pigs (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK)

Ketokel vet 100 mg/ml, solution for injection for cattle, horses and pigs (NO)

Vetaprofen 100 mg/ml, solution for injection for cattle, horses and pigs (PL)

Kelafen 100 mg/ml, solution for injection for cattle, horses and pigs (DK)

Fenprokel vet 100 mg/ml, solution for injection for cattle, horses and pigs (FI, SE)

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains :

Active substance :

Ketoprofen 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml - 100 ml - 250 ml

5. TARGET SPECIES

Horse, cattle, pig

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use

Horses: intravenous use

Pigs: deep intramuscular use

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal:

- following intravenous administration: 1 day

- following intramuscular administration: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Milk: Not authorised for use in lactating animals producing milk for human consumption

Pigs:

Meat and offal: 2 days

9. SPECIAL WARNING, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Shelf life after first opening the container: 28 days.

Once broached, use by...

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

Protect from light.

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

Dispose of waste material 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.

To be administered only by a veterinary surgeon (ES).

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

KELA N.V., St. Lenaartseweg 48, 2320 Hoogstraten, BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelaprofen 100 mg/ml, solution for injection for cattle, horses and pigs (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK)

Ketokel vet 100 mg/ml, solution for injection for cattle, horses and pigs (NO)

Vetaprofen 100 mg/ml, solution for injection for cattle, horses and pigs (PL)

Kelafen 100 mg/ml, solution for injection for cattle, horses and pigs (DK)

Fenprokel vet 100 mg/ml, solution for injection for cattle, horses and pigs (FI, SE)

Ketoprofen

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains :

Active substance :

Ketoprofen 100 mg

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

50 ml

4. ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use

Horses: intravenous use

Pigs: deep intramuscular use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal:

- following intravenous administration: 1 day

- following intramuscular administration: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Milk: Not authorised for use in lactating animals producing milk for human consumption

Pigs:

Meat and offal: 2 days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

Shelf life after first opening the container: 28 days.

Once broached, use by:...

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 100 – 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK:

Kelaprofen 100 mg/ml, solution for injection for cattle, horses and pigs

NO:

Ketokel vet 100 mg/ml, solution for injection for cattle, horses and pigs

PL:

Vetaprofen 100 mg/ml, solution for injection for cattle, horses and pigs

DK:

Kelafen 100 mg/ml, solution for injection for cattle, horses and pigs

FI, SE:

Fenprokel vet 100 mg/ml, solution for injection for cattle, horses and pigs

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains :

Active substance :

Ketoprofen 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml – 250 ml

5. TARGET SPECIES

Horse, cattle, pig

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use

Horses: intravenous use

Pigs: deep intramuscular use

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal:

- following intravenous administration: 1 day
- following intramuscular administration: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Milk: Not authorised for use in lactating animals producing milk for human consumption

Pigs:

Meat and offal: 2 days

9. SPECIAL WARNING, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Shelf life after first opening the container: 28 days.

Once broached, use by:...

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

Protect from light.

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

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

KELA N.V., St. Lenaartseweg 48, 2320 Hoogstraten, BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot: