

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 250 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOPROCEN 150 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 150 mg

3. PACKAGE SIZE

100 ml

250 ml

4. TARGET SPECIES

Cattle, pigs and horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: Intravenous or intramuscular use.

Pigs: Intramuscular use.

Horses: Intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 3 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

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 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

CENAVISA, S.L.

14. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOPROCEN 150 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 150 mg

3. TARGET SPECIES

Cattle, pigs and horses.

4. ROUTES OF ADMINISTRATION

Cattle: Intravenous or intramuscular use.

Pigs: Intramuscular use.

Horses: Intravenous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 3 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Use by:

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

CENAVISA, S.L.

9. BATCH NUMBER

Lot {number}