

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box
Glass vial 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketosol-100, 100 mg/ml solution for injection for cattle, pigs and horses (EE, BG, HR, LV, RO, SI and SK)

Ketoject, 100 mg/ml solution for injection for cattle, pigs and horses (IT, PL and HU)

Ketoject 100 mg/ml solution for injection for cattle, pigs and horses (CZ)

Ketosol, 100 mg/ml solution for injection for cattle, pigs and horses (CY, DE, EL, ES, FR, IE, LU, NL, PT)

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

Ketochemie, 100 mg/ml solution for injection for cattle, pigs and horses (AT, BE, DK, FI)

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen.....100,0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs, horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

On the Cardboard box: For intramuscular use (cattle, pig), for intravenous use (cattle, horse).

On the Vial: Intramuscular (cattle, pig), intravenous (cattle, horse).

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle: Meat and offal: 4 days

Milk: zero hours.

Horses: Meat and offal: 4 days.

Not authorized for use in mares producing milk for human consumption.

Pigs: Meat and offal: 4 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days.

Once broached use by...

11. SPECIAL STORAGE CONDITIONS

Store in the original package, protected from light.

After first opening the immediate packaging do not store above 25 °C.

12. SPECIAL 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.

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

Interchemie Werken De Adelaar Eesti AS

Vanapere tee 14, Püünsi, Viimsi

Harju County 74013

Estonia

Tel.: +372 6 005 005

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER’S BATCH NUMBER

Batch {number}