

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TILMI-kel 300 mg/ml solution for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tilmicosin 300 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

100 ml

250 ml

5. TARGET SPECIES

Cattle

6. INDICATIONS

Read the fold out label before use.

7. METHOD AND ROUTE OF ADMINISTRATION

For subcutaneous injection only.

Read the fold out label before use.

8. WITHDRAWAL PERIOD

Read the fold out label before use.

9. SPECIAL WARNINGS, IF NECESSARY

Accidental injection is dangerous.

Read the fold out label before use.

Operator Safety Warnings:

INJECTION OF TILMICOSIN IN HUMANS CAN BE FATAL – EXERCISE EXTREME CAUTION TO AVOID ACCIDENTAL SELF-INJECTION AND FOLLOW THE ADMINISTRATION INSTRUCTIONS AND THE GUIDANCE BELOW PRECISELY

- This product should only be administered by a veterinary surgeon.
- Never carry a syringe loaded with TILMI-kel with the needle attached. The needle should be connected to the syringe only when filling the syringe or administering the injection. Keep the syringe and needle separate at all other times.
- Do not use automatic injection equipment.
- Ensure that animals are properly restrained, including those in the vicinity.
- Do not work alone when using TILMI-kel.

In case of self-injection SEEK IMMEDIATE MEDICAL ATTENTION and take the vial or the fold out label with you. Apply a cold pack (notice directly) to the injection site.

NOTE TO PHYSICIAN: please see inside of the fold out label for details.

Additional operator safety warnings:

- Avoid contact with skin and eyes. Rinse any splashes from skin or eyes immediately with water.
- May cause sensitisation by skin contact. Wash hands after use.

10. EXPIRY DATE

EXP

Once opened, use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C. Do not freeze.

After withdrawal of the first dose, the product should not be stored above 25 °C.

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 national 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.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER



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

16. MARKETING AUTHORIZATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot