

Veterinary Medicine Package Leaflet

This medicine is dispensed with a veterinarian's prescription only

For use in animals only

1. NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE

Tolfine Solution for Injection Veterinary, 4%

2. ACTIVE INGREDIENT and amount per dosage unit

tolfenamic acid 40 mg/1 mL

Inactive ingredients

benzyl alcohol 10.4 mg/1 ml

For the full list of inactive ingredients, see Section 13: 'Additional information'.

3. WHAT IS THIS MEDICINE INTENDED FOR

An anti-inflammatory, anti-pyretic, and analgesic indicated for use in cattle as an adjunct in the treatment of acute mastitis concomitantly with antibacterial therapy, and in pigs as an adjunct in the treatment of the metritis mastitis agalactia (MMA) syndrome concomitantly with antibacterial therapy.

Therapeutic group: non-steroidal anti-inflammatory drugs (NSAIDs)

4. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient or to any of the inactive ingredients listed in section 13.

5. SIDE EFFECTS

There are reports of collapse following rapid intravenous injection in cattle.

When administering intravenously, the medicine should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

Transient inflammation and swelling may commonly occur at the injection site lasting up to 38 days.

Hypersensitivity reactions, including anaphylaxis (a severe allergic reaction, sometimes fatal), have been reported very rarely. The frequency of side effects is defined according to the following conventions:

- very common effects (more than 1 in 10 animals treated displayed side effects)
- common effects (more than 1 but less than 10 in 100 animals treated)
- uncommon effects (more than 1 but less than 10 in 1,000 animals treated)
- rare effects (more than 1 but less than 10 in 10,000 animals treated)
- very rare effects (less than 1 in 10,000 animals treated, including isolated reports).

If you notice any serious side effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

6. TARGET ANIMALS: Cattle, pigs

7. DOSAGE AND METHOD OF ADMINISTRATION

Cattle: mastitis – 4 mg/kg of body weight (1 ml/10 kg of body weight) by intravenous injection. Use for conditions other than mastitis: 2 mg/kg of body weight (1 ml/20 kg

of body weight) by intramuscular injection in the neck area.

Pigs: MMA Syndrome – 2 mg/kg of body weight (1 ml/20 kg of body weight) – by injection into the neck muscle.

8. HOW TO USE THIS MEDICINE

For intravenous or intramuscular injection.

9. WITHDRAWAL PERIOD

- Cattle: meat – 3 days. milk – 24 hours.
- Pigs: meat – 3 days.

10. WARNINGS

Special warnings about treating the target animal with this medicine

- Do not inject more than 20 ml at the same site when given by the intramuscular (I.M.) route.

Special warnings about the safety of using this medicine in animals

- Do not exceed the recommended dosage and duration of treatment.
- Use aseptic precautions when administering the medicine.
- Avoid the introduction of contamination during use. Should any apparent growth of microorganisms or discolouration occur, the medicine should be discarded.

Special safety precautions for the person administering this medicine

- No information available

Gestating and lactating animal patients

- May be used during gestation and lactation.

Drug interactions and other interactions

- Do not administer other nonsteroidal anti-inflammatory drugs (NSAIDs) concurrently. Wait at least 24 hours between drugs.
- Tolfenamic acid is highly bound to plasma proteins and may compete with other highly bound drugs.

Overdose

No information available

Incompatibility

In the absence of compatibility tests, this veterinary medicine should not be mixed with other veterinary medicines.

11. STORAGE INSTRUCTIONS

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.
- After first opening, the medicine may be used for up to 28 days.

12. INSTRUCTIONS FOR DISPOSAL OF THE MEDICINE/REMAINING MEDICINE AT THE END OF ITS USE

Dispose of any remaining veterinary medicine or waste obtained from using a veterinary medicine in the same manner as toxic waste; do not discard into a sewer/down a drain.

13. ADDITIONAL INFORMATION

- In addition to the active ingredient, this medicine also contains:
Diethylene glycol monoethyl ether, benzyl alcohol, ethanolamine, water for injection
- What the medicine looks like and contents of the pack:
Clear and slightly viscous solution, colorless to slightly yellowish, in a 10 ml, 50 ml, 100 ml or 250 ml vial, with a rubber stopper, packaged in a carton box. Not all pack sizes may be marketed.

Registration holder's name and address: Eliezer Linevitz Ltd., 6 Adom St., P.O.B 7006, Kanot Industrial Area.

Manufacturer's name and address: Vetoquinol, BP 189, 70204 Lure Cedex, France

Registration number of the medicine in the Ministry of Health National Drug Registry:
082-44-92298-00

Revised in July 2025.