

Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. NAME OF THE VETERINARY MEDICINE, FORM AND STRENGTH

TOLFINE SOLUTION FOR INJECTION VETERINARY, 4%

2. ACTIVE INGREDIENT and its quantity in a dose unit

Tolfenamic Acid 40 mg/ 1 mL

Inactive ingredients : Each mL contains:

Benzyl alcohol 10.4 mg

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

3. WHAT IS THE MEDICINE INTENDED FOR

An anti-inflammatory, anti-pyretic, pain-alleviating solution indicated for use in cattle for the treatment of acute mastitis concomitantly with antibacterial therapy, and in pigs for the treatment of the Metritis Mastitis Agalactia 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, to any of the inactive ingredients listed in section 13.

5. SIDE EFFECTS

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

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

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: <https://sideeffects.health.gov.il>

6. TARGET SPECIES

Cattle, Pigs

7. DOSAGE AND ADMINISTRATION ROUTE

Cattle: mastitis – 4 mg / kg of bodyweight (1 ml / 10 kg of bodyweight) by intravenous injection. Use for conditions other than mastitis: 2 mg / kg of bodyweight (1 ml / 20 kg of bodyweight) via intramuscular route in the neck area.

Pigs: MMA Syndrome – 2 mg / kg of bodyweight (1 ml / 20 kg of bodyweight) – via intramuscular injection in the neck.

8. HOW TO USE THE PRODUCT

For intravenous or intramuscular injection.

9. WITHDRAWAL PERIOD

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

10. WARNINGS

Special warnings for safe use in target animals

- Do not inject more than 20 ml at the same site.

Special precautions for use in animals

- Do not exceed the recommended dosage and duration of treatment.
- Use aseptic precautions when administering the product.

Special precautions regarding human safety of persons administering the medicinal product

- None known.

Pregnancy or lactation of the treated animal

- The product may be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

- Do not administer other NSAIDs concurrently or within 24 hours of each other.
- Tolfenamic acid is highly bound to plasma proteins and may compete with other highly bound drugs.

Overdose

- None known.

Incompatibility

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

11. STORAGE INSTRUCTIONS

- Avoid poisoning! Keep this medicine and any other medicine in a closed place out of reach and sight of children and/or infants to avoid poisoning.
- Do not use this medicine after the expiry date shown on the package. The expiry date refers to the last day of the month indicated.
- Store below 25°C. Protect from light.
- After first opening, the product may be used for 28 days.

12. INSTRUCTIONS FOR DISPOSING OF THE PRODUCT / REMAINING PRODUCT AT THE END OF ITS USE

Any unused veterinary medicinal product or waste materials derived from veterinary medicinal product use, should be disposed of as toxic waste. Do not throw into the sewage system.

13. ADDITIONAL INFORMATION

- In addition to the active substances, the medicine includes also: Diethylene glycol monoethyl ether, Benzyl Alcohol, Ethanolamine, Water for Injections.
- How does the medicine look like and what is the content of the package – 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 package sizes may be marketed.

Registration holder: Eliezer Linevitz Ltd., Adom 6 st., P.O.B 7006, Kanot Industrial Area

Manufacturer's name and address: VETOQUINOL, BP 189, 70204 LURE CEDEX, FRANCE

Registration number of this medicine in the Ministry of Health State Medicine Registry: 082-44-92298

Revised in July 2022 according to MoHs guidelines.