Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFINE SOLUTION FOR INJECTION VETERINARY

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Tolfenamic acid 40 mg

Excipients
Benzyl alcohol 10.4 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Pigs.

4.2 Indications for use, specifying the target species

Anti -inflammatory, antipyretic and analgesic, indicated for:
- in cattle, as an adjunct in the treatment of acute mastitis, in combination with antibacterial treatment.

- in pigs, as an adjunct in the treatment of Metritis Mastitis Agalactia syndrome, in combination with antibacterial treatment.
.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings for each target species

Do not exceed 20 ml per injection site.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the stated dosage and duration of treatment.

Use aseptic precautions when administering the product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None known.

4.6 Adverse reactions (frequency and seriousness)

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.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il/

4.7 Use during pregnancy, lactation or lay

The product may be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

For other uses than mastitis in cattle, the recommended dosage is 2 mg/kg bodyweight (1 ml/20 kg bodyweight) by intramuscular injection into the neck area.

For use in mastitis in cattle, the recommended dosage is 4 mg/kg bodyweight (1ml per 10 kg bodyweight) as a single IV injection.

In pigs, the recommended dosage is 2 mg/kg bodyweight (1ml/20 kg bodyweight) as a single intramuscular injection into the neck muscle.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Cattle
I.M. injection
Meat and offal: 3 days.
Milk: 24 hours.

I.V. injection
Meat and offal: 3 days.
Milk: 24 hours.

Pigs
Meat and offal: 3 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Musculo-skeletal system, antiinflammatory and antirheumatic products, non-steroids, fenamates, tolfenamic acid.

ATC vet code: QM01AG02.

5.1 Pharmacodynamic properties

Tolfenamic acid (N-(2-methyl-3-chlorophenyl) anthranilic acid) is a non-steroidal anti-inflammatory drug (NSAID) belonging to the fenamate group. Tolfenamic acid exerts anti-inflammatory, analgesic and antipyretic activities.

The anti-inflammatory activity of tolfenamic acid is mainly due to an inhibition of cyclo-oxygenase and thus to a reduction of the synthesis of prostaglandins and thromboxanes, which are important inflammatory mediators.

5.2 Pharmacokinetic particulars

In cattle and pigs, tolfenamic acid injected by IM route at a dose of 2mg/kg is rapidly absorbed from the injection site with mean maximum plasma concentrations of about 1.4 µg/ml in cattle and 2.3 µg/µλ in pigs obtained at about 1 hour.

The volume of distribution is about 1.3 1/kg in cattle and pigs.

It is extensively bound to plasma albumin (>97%).

Tolfenamic acid is distributed in all the organs with a high concentration in the plasma, digestive tract, liver, lungs and kidneys.
However, the concentration in the brain is low. Tolfenamic acid and its metabolites do not cross the placenta to any great extent.

Tolfenamic acid distribution involves extracelluar fluids where concentrations similar to plasma are achieved both in healthy and inflamed peripheral tissues. It also appears in milk in the active form, mainly associated with the curds.
Tolfenamic acid undergoes extensive enterohepatic recirculation and, as a result prolonged concentrations are found in plasma.

The elimination half life varies from 3-5 hours in pigs to 8 - 15 hours in cattle.

In cattle and pigs, tolfenamic acid is eliminated mainly unchanged in faeces (~30%) and urine (~70%).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Diethylene glycol monoethyl ether
Benzyl Alcohol
Ethanolamine
Water for Injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

The product Tolfine is packaged in type I glass vials of 10 ml, 50 ml, 100 ml and 250 ml.
The vials are closed with a chlorobutyl rubber stopper with aluminium flip cap.
Each vial is packaged in a cardboard box.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Manufacturer: VETOQUINOL, BP 189, 70204 LURE CEDEX, FRANCE

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

Revised in July 2022 according to MoHs guidelines.