1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfine 40 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Tolfenamic acid 40 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	10.4 mg
Ethyldiglycol	
Ethanolamin	
Water for injection	

Clear, colourless to slightly yellow, slightly viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

In cattle:
as an adjunct in the treatment of pneumonia by improving general conditions and nasal discharge and
as an adjunct in the treatment of acute mastitis.

In pigs:
as an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipeients.

3.4 Special warnings

Do not exceed 20 ml per injection site.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not exceed the stated dosage and duration of treatment.
Use aseptic precautions when administering the veterinary medicinal product.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated):	Injection site inflammation[1], injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction[2] (anaphylaxis[2]) Collapse[3]

[1] Transient and lasting up for 38 days.
[2] Sometimes fatal.
[3] Following rapid intravenous injection. When administering intravenously, the veterinary medicinal product should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

Pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site inflammation[1], injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction[2] (anaphylaxis[2])

[1] Transient and lasting up for 38 days.
[2] Sometimes fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Pigs: Intramuscular use.
Cattle: Intramuscular or intravenous use.

In cattle, for inflammation associated with respiratory disease the recommended dosage is 2 mg/kg (1 ml/20 kg bodyweight) by intramuscular injection into the neck area. Treatment may be repeated once after 48 hours.

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

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle: Intramuscular injection:
Meat and offal: 12 days.
Milk: 0 hours.

Cattle: Intravenous injection:
Meat and offal: 4 days.
Milk: 24 hours.

Pigs:
Meat and offal: 16 days.

4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

4.1 ATCvet code :
QM01AG02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

In cattle and pigs, tolfenamic acid injected by **i.m**. route at a dose of 2 mg/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/ml 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 extracellular 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%).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is packaged in amber type I glass vials of 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.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as tolfenaminic acid may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/023/001

8. DATE OF FIRST AUTHORISATION

04/02/2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/06/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).