1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trippel-Oxy 150 mg/ml solution for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

150 mg Oxytetracycline Hydrochloride

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Magnesium chloride	
Monoethanolamine	
Sodium formaldehyde sulfoxylate	
Dimethylacetamide	to 1 ml
Water for injections	

A clear light amber solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is recommended in the treatment of a wide range of common systemic, respiratory and local infections caused by, or associated with, organisms sensitive to oxytetracycline.

3.3 Contraindications

Do not use in sheep producing milk for human consumption.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer intravenously.
Do not use in horses, dogs and cats.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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

Wash hands after use.
This product contains dimethylacetamide (DMAC) and care should be taken to prevent absorption through the skin.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep and pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site reaction[1]
Rare (1 to 10 animals / 10,000 animals treated):	Allergic reactions

[1]Transient

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Use of tetracycline during the period of tooth development, including late pregnancy, may lead to tooth discoloration.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product should not be diluted or mixed with solutions of calcium salts.

3.9 Administration routes and dosage

For intramuscular use only.
The recommended dosage is 5 mg oxytetracycline per kg or 3.5 ml per 100 kg bodyweight. To ensure a correct dosage, body weight should be determined as accurately as possible.

SPECIES	DOSE (ml) / kg bodyweight
Cow	3.5 ml / 100 kg
Calf	1.75 ml / 50 kg
Sheep	1.0 ml / 25 kg
Lamb	0.5 ml / 10 kg
Piglet	0.25 ml / 5 kg

These are average recommendations. The period of treatment should extend from 3-5 days, depending on the severity of the condition being treated. The recommended maximum duration of therapy is 5

days. If the injection volume exceeds 25 ml, divide the dose and administer at two separate injection sites.

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

Do not exceed the stated dose.

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
Milk: 96 hours.
Meat and offal: 28 days.

Sheep
Milk: Not to be consumed.
Meat and offal: 28 days.

Pigs
Meat and offal: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01AA06

4.2 Pharmacodynamics

Oxytetracycline is a bacteriostatic antibiotic with a broad range of antibacterial activity.

4.3 Pharmacokinetics

Oxytetracycline is rapidly absorbed from the injection site with peak plasma levels within 2 hours. Therapeutic plasma levels are maintained for 24 hours post treatment.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

The veterinary medicinal product should not be diluted or mixed with solutions of calcium salts.

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

Do not store above 25ºC.

Do not freeze.

5.4 Nature and composition of immediate packaging

100 ml amber, type II glass vial, closed with a grey nitryl stopper and aluminium seal.
Presentations: 12 x 100 ml and 25 x 100 ml.

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.

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

Univet Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10990/037/001

8. DATE OF FIRST AUTHORISATION

01 October 1998

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

31 October 2024

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).