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# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LIMOXIN WS 1000 mg/g, powder for oral solution for calves, goats, sheep, chickens, turkeys and swine

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g powder contains:

**Active substance:**
Oxytetracycline hydrochloride 1000 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

A yellow water soluble powder for oral administration through drinking water.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pre-ruminant calves, goats, sheep, chickens (broilers), turkeys and swine.

### 4.2 Indications for use, specifying the target species

Gastrointestinal and respiratory infections caused by oxytetracycline sensitive bacteria like *Bordetella*, *Bacillus*, *Corynebacterium*, *Campylobacter*, *E. coli*, *Haemophilus*, *Pasteurella*, *Salmonella*, *Staphylococcus* and *Streptococcus* spp. and *Mycoplasma*, *Rickettsia* and *Chlamydia* spp. in pre-ruminant calves, goats, poultry (broilers and turkeys), sheep and swine.

### 4.3 Contraindications

Do not use in case of hypersensitivity to tetracyclines.
Do not use to animals with a seriously impaired hepatic and/or renal function and in animals with gastrointestinal hypomotility.
Do not administer with penicillins, cephalosporins, quinolones and cycloserine.
Do not administer to animals with active microbiological digestive system (rabbits, guinea pigs, hamsters, chinchillas or other small herbivorous animals).

### 4.4 Special warnings for each target species

For pre-ruminant animals only.

## 4.5 Special precautions for use

Special precautions for use in animals
Use of the product should be based on susceptibility testing and it should take into account official and local antimicrobial policies.
Cannot be used in subtherapeutic doses.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to tetracyclines should avoid contact with this product.
During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided.
Personal protective equipment consisting of dusk mask and impervious gloves (e.g. rubber or latex) should be worn when handling the veterinary medicinal product.
In case of accidental ingestion, eye contact or if you develop symptoms following exposure such as skin rash, you should seek medical advice and show the package leaflet or label to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.
Handle this product with great care, taking all recommended precautions.

## 4.6 Adverse reactions (frequency and seriousness)

Discoloration of teeth in young animals.
Hypersensitivity reactions may occur.

## 4.7 Use during pregnancy, lactation or lay

Animal studies do not indicate embryotoxic or teratogenic effects.
Oxytetracycline crosses the mammalian placental barrier and can cause tooth discoloration and retard embryo development. Tetracyclines are also found in breast milk.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

## 4.8 Interaction with other medicinal products and other forms of interaction

Chelates formed with divalent and trivalent cations may inhibit the antimicrobial activity and uptake of oxytetracycline in the gastrointestinal tract. Bioavailability can be improved by the addition of citric acid or sodium terephthalate.
Co-administration of tetracyclines with bactericidal antibiotics (penicillins, cephalosporins, trimethoprim) may antagonize their activity.

## 4.9 Amounts to be administered and administration route

For oral administration with drinking water.

Calves, goats and sheep : 20 mg oxytetracycline per 1 kg of bodyweight, i.e. twice daily 1 g powder through drinking water per 50 mg of bodyweight for 3 - 5 days.
Poultry and swine : 20 mg oxytetracycline per 1 kg of bodyweight daily, i.e. 1 kg powder per 5000 litres of drinking water for 3 - 5 days.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Consumption depends on the physiological and clinical condition of the animals. Oxytetracycline levels should be adjusted accordingly in order to provide the animals with the correct dose.
For pre-ruminant calves, lambs and kids only.

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

Acute overdoses can result in nephrotoxicity.

### 4.11 Withdrawal period(s)

Meat and offal:
Calves, goats, sheep and swine : 8 days.
Chickens : 6 days.
Turkeys : 9 days.
Not for use in birds producing or intended to produce eggs for human consumption.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use (tetracyclines – oxytetracycline).
ATC vet code: QJ01AA06.

### 5.1 Pharmacodynamic properties

Oxytetracycline belongs to the group of tetracyclines and has broad-spectrum bacteriostatic activity against many Gram-positive and Gram-negative bacteria, such as *Bordetella*, *Campylobacter*, *Chlamydia*, *E. coli*, *Haemophilus*, *Mycoplasma*, *Pasteurella*, *Rickettsia*, *Salmonella*, *Staphylococcus* and *Streptococcus* spp. The action of oxytetracycline is based on the inhibition of bacterial protein synthesis.

### 5.2 Pharmacokinetic particulars

When administered orally, oxytetracycline is readily absorbed and achieves effective concentrations in various tissues. It is excreted mainly in urine, for a small part in bile and, in lactating animals, in milk.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None.

### 6.2 Major incompatibilities

No major incompatibilities are known.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 2 weeks.
Shelf life after dilution or reconstitution according to directions: 24 hours.

### 6.4. Special precautions for storage

Store below 25 °C in a dry place.
Protect from direct sunlight. Keep the jar tightly closed.

### 6.5 Nature and composition of immediate packaging

Aluminium foil heat-sealed laminated sachet containing 100 g.
HDPE jar with PE jaycap containing 500 or 1000 g.
Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

## 7. MARKETING AUTHORISATION HOLDER

UAB „Interchemie werken „De Adelaar" LT"
Vinčų g. 3-48, 46297 Kaunas
Lithuania

## 8. MARKETING AUTHORISATION NUMBER(S)

LT/2/18/2445/001-003

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12/02/2018

## 10 DATE OF REVISION OF THE TEXT

12/02/2018

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.