SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Brand Name: VETOXY 20

Generic name: OXYTETRACYCLINE HCL 20 %

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Each gram contains Oxytetracycline Hydrochloride 200mg.

Full excipients list at 6.1

3. PHARMACEUTICAL FORM

Powder for oral administration through drinking water

4. CLINICAL PARTICULARS

4.1 Target species

Calves, Lamb, Goat kids, Pigs, and Poultry

4.2 Therapeutic indications

Vetoxy 20 is used in the treatment of infections caused by gram-positive and gramnegative bacteria (Staphylococcus, B. Haemolytic streptococcus, non-haemolytic streptococcus, Brucella, Pastteurella, clostridia, klebsiella, Haemophylus, Corynebacterium,E. Coli and Salmonella) Mycoplasma, Spirochetosis and actinomycces. Also active against Rickettsia.

4.2 Posology and method of administration

For oral administration only.

This product is administered orally in drinking water

4.4 Contraindications

Oxytetracycline should not be used in animals with known hypersensitivity or allergy

to the drug. Should be used with caution in pets with liver or kidney (renal)

disease.

At high doses, oxytetracycline causes gastrointestinal disorder.

Oxytetracycline may interact with other calcium medications. High doses of oxytetracycline

can cause kidney injury.

Oxytetracycline should be avoided in pregnant animals as liver problems may

occur.

4.5 Special warnings and precautions for use

- Wash hands after use.
- Do not exceed the above-mentioned dosage.
- Keep out reach of children.
- The most frequent concern in people from administration of tetracyclines is that it will affect bone and teeth development in young animals.
- High doses of oxytetracycline can cause kidney injury.Oxytetracycline should be avoided in pregnant animals as liver problems may occur.

4.6 Interaction with other medicinal products and other forms of interaction

Oxytetracycline may interact with other calcium medications

4.7 Undesirable effects

Side effects are mainly gastrointestinal and photosensitive allergic reactions common to the tetracycline antibiotics group. It can also damage calcium-rich organs, such as teeth and bones, although this is very rare

4.8 Overdose

High doses of oxytetracycline can cause kidney injury.

4.9 Withdrawal Periods

- Meat – 7 days
- Eggs – Not recommended for use in hens laying eggs for human consumption

5. PHARMACOLOGICAL PROPERTIES

Oxytetracycline is known as a broad-spectrum antibiotic due to its activity against such a wide range of infections. It was the second of the tetracyclines to be discovered. Oxytetracycline, like other tetracyclines, is used to treat many infections common and rare. Its better absorption profile makes it preferable to tetracycline for moderately severe infections.

Mechanism of action

Oxytetracycline inhibits cell growth by inhibiting translation. It binds to the 30S ribosomal subunit and prevents the amino-acyl tRNA from binding to the A site of the ribosome. The binding is reversible in nature. Oxytetracycline is lipophilic and can easily pass through the cell membrane or passively diffuses through porin channels in the bacterial membrane.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Bentonite
- Sodium Benzoate BP
- BHT (white) BP

- Aerosil 200 BP
- Dextrose Monohydrate

6.2 Incompatibilities

Do not combine with other antibiotics like penicillin and cephalosporin

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30oC in a dry place away from direct light

6.5 Nature and contents of container

Sachet containers: 100g

Application for Registration of Veterinary Medicinal Products

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

7.1 Marketing authorization holder

VETCARE KENYA LTD

Address: P.O Box 63405 – 00619 Nairobi

Country: Kenya

7.2 Manufacturing site addresses

VETCARE KENYA LTD

Winsford Park, BabaDogo Road

P.O. BOX 63405 00619 Nairobi, Kenya

7.3 Marketing Authorization Number

Rwanda FDA-VMP-MA-005

7.4 Date of first Authorization/renewal of the Authorization

Date of first Authorization in Rwanda: 22nd March 2022

7.5 Date of revision of the text

11th April 2022