1. NAME OF THE MEDICINALPRODUCT

Enrofloxacin 20% oral solution (Kattle care Enrofloxacin oral solution -20%)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 1 ml contains 200 mg of enrofloxacin, for the full list of excipients, see section 6.1

3. PHARMACEUTICALFORM

Oral solution- A pale yellow clear liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gastrointestinal infections, respiratory infections and urinary tract infections caused by enrofloxacin sensitive micro-organisms, like Campylobacter, E. coli, Haemophilus, Mycoplasma, Pasteurella and Salmonella spp. in calves, goats, poultry, sheep and swine.

4.2 Posology and method of administration

For oral administration via drinking water.

Poultry: 100 ml per 400 litres of drinking water for 3 – 5 days.
Pigs: 100 ml per 200 – 600 litres of drinking water for 3 – 5 days.
Calves, sheep, goats: 5 ml per 75 –150 kg bodyweight, twice daily, during 3 – 5 days.
Medicated drinking water should be used within 24 hours.
Note: for pre-ruminant calves, lambs and kids only.
Not for use in birds producing eggs for human consumption.

4.3 Contraindications

Hypersensitivity to enrofloxacin.
Administration to animals with a seriously impaired liver and/or renal function.
Concurrent administration of tetracyclines, chloramphenicol, macrolides and lincosamides.

4.4 Special warnings and precautions for use

Official and local antimicrobial policies should be taken into account when the product is used.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of

antimicrobials.
Whenever possible fluoroquinolones should only be used based on susceptibility testing.
Use of the product including use deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all fluoroquinolones due to the potential for cross-resistance.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight during 14 days.
The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated to clinical signs.

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

People with known hypersensitivity to fluoroquinolones should avoid any contact with the product.
Avoid skin and eye contact. Wash any splashes from skin or eyes immediately with water.
Wash hands after use. Do not eat, drink or smoke whilst handling the product

4.5 Interaction with other medicinal products and other forms of interaction

Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g., macrolides, tetracyclines or phenicols).
Do not use concurrently with theophylline as the elimination of theophylline may be delayed.

4.6 Pregnancy and Lactation

Laboratory studies in rats have not produced any evidence of teratogenic effects.
Studies performed in female rabbits do not show teratogenic effects on the foetus and the mother.
Studies carried out in lactating rabbits do not show toxic effects for the lactating young rabbits within the first 16 days. Rabbits older than this age have the ability to eliminate enrofloxacin.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Digestive tract disorders (e.g., diarrhoea) may occur in very rare cases. These signs are generally mild and transient.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.9 Overdose

At the dosage of twice the recommended dosage administered for 15 days (3 times the recommended duration of treatment) adverse reactions were not observed. In case of over dosage, the symptoms would be a weak stimulation of the spontaneous motility, so the treatment should be ceased. Overdose by fluoroquinolones may cause sickness, vomiting and diarrhoea.
The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

Withdrawal period(s)
Not for use in birds producing eggs for human consumption.
Chickens: Meat and offal: 7 days
Turkeys: Meat and offal: 13 days
Calves, sheep, goats and pigs: Meat and offal: 12 days

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: quinolone and quinoxaline antibacterials, fluoroquinolones

ATCvet Code: QJ01MA90

4.10 Pharmacodynamic properties

Mode of action
Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum
Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* spp., *Actinobacillus pleuropneumoniae*,*Mannheimia haemolytica*, *Pasteurella*spp. (e.g., *Pasteurella multocida*), against Gram-positive

bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

4.11 Pharmacokinetic properties

Enrofloxacin was well absorbed after oral administration to rats and the target species. In rats, the bioavailability of enrofloxacin was estimated to be 75% after a single oral dose of 5 mg/kg bw of radio labelled enrofloxacin. The substance was widely distributed to all tissues with highest concentration in the liver and kidney. Elimination was rapid via both urine and faeces. Most of the administered radio activity was excreted during the first 24 hours after administration. Raturine after dosing (5 times 5 mg/kg bw/day) with ^{14}C-enrofloxacin contained the following substance: enrofloxacin (17%), ciprofloxacin (31%), oxociprofloxacin (5%), enrofloxacin amide (23%), dioxociprofloxacin (9%), desethylene ciprofloxacin (3%), desethylene enrofloxacin (2%), N-formyl ciprofloxacin (less than 2%), oxoenrofloxacin (less than 2%) and hydroxyoxo enrofloxacin (3%).

5.3 Preclinical safety data

Not Applicable

5. PHARMACEUTICALPARTICULARS

5.1 List of excipients

Sodium formaldehyde sulfoxylate
Benzyl alcohol
Ethanol
Sodium hydroxide
Propylene glycol
Sorbitol
Purified water

5.2 Incompatibilities

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

5.3 Shelf life

24 months

5.4 Special precautions for storage

Store in a tightly sealed container, protected from light, and at the temperature below 30°C.

Nature and contents of container <and special equipment for use, administration or implantation>

1000 ml/100ml HDPE bottle.

5.5 Special precautions for disposal <and other handling>

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

6. <APPLICANT/MANUFACTURER>

KATTLE CARE LIMITED

Plot 6 Abimbola Way,

Isolo Industrial Estate,

Isolo, Lagos, Nigeria

E-mail: kattlecare2017@gmail.com

Manufacturer:

Name of the manufacturer: Shijiazhuang Fengqiang Animal Pharmaceutical Co., Ltd
Address: No. 16 Zhenzhu Road, Xinzhaidian Industry Park, Zhaoxian County, Shijiazhuang,
Hebei, China 050035
Tel: +86 13373316552
Fax: +86 (0)311 84752785
Email: admin@fq-pharm.com