1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Structure of the Summary of Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Generic name: Oxytetracycline bolus 500mg/7g

Brand name: Sinoxy

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bolus Contains:

Oxytetracycline: 500mg;

Starch: 2600mg;

Dextrose: 1440mg;

Magnesium stearate: 60mg;

Calcium carbonate: 1400mg;

Sucrose: 1000mg

3. PHARMACEUTICAL FORM

Bolus.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, calves, cattle, sheep and goat.

4.2 Indications for use, specifying the target species

SINOXY is indicated for the treatment of bacterial enteritis caused by E.coli and Salmoonella spp. In calves, lambs, kids and horses.

SINOXY is also indicated for the treatment of various systemic bacterial infections caused by oxytetracycline sensitive microorganisms.

4.3 Contraindications

The drug should not be used with penicillin. Do not exceed the recommended dose.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special Precautions for use in animals:

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.

Official and local antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to oxytetracycline.

ii) Special precautions to be taken by the person administering the product to the animals:

Wash hands after use. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

4.6 Side effects

Oxytetracycline is generally safe and effective when prescribed by a veterinarian, although it can cause side effects in some animals like swelling of eyelids, vulva,scrotum, ears and anus. It can also cause restlessness in some animals.

4.7 Use during pregnancy, lactation or lay

Oxytetracycline can retard skeletal growth of the fetus if administered during pregnancy.

The use of tetracyclines during the period of tooth development, including late pregnancy, may lead to tooth discolouration.

Tetracyclines are excreted in milk.

The product should only be used according to the benefit/risk assessment by the responsible veterinary surgeon.

4.8 Interaction with other medicinal products and other forms of interaction

Dilution with calcium salts will cause precipitation and should be avoided.

Oxytetracycline may interfere with the action of bactericidal antimicrobials, such as penicillins and cephalosporins, and therefore they should not be used simultaneously.

4.9 Amount(s) to be administration and administration route

Oral administration.

1 bolus of SINOXY/20-45kg body weight (10-20mg oxytetracycline base/1kg body weight) for 3-5 days.

4.10 Overdose

There is no known specific antidote. If signs of possible overdose occur, treat the animal symptomatically.

4.11 Withdrawal period(s)

- For meat: 27 days.

Sinoxy should not be administered in lactating cattle.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATCvet code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is active against a wide range of Gram positive and Gram negative pathogenic bacteria, and certain Rickettsia. Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the amino-acyl transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of the amino acids to the elongating peptide chain, inhibiting protein synthesis.

5.2 Pharmacokinetic properties

Oxytetracycline is widely distributed in the body, including to the kidneys, liver, lungs and muscle, though only small quantities are distributed to the CSF. The placenta is readily passed by oxytetracycline

and concentration in the fetal blood may reach that of the maternal circulation. Oxytetracycline apparently is not metabolised in vivo and is eliminated primarily unchanged, via glomerular filtration. It is also excreted into the GI tract via both biliary and non-biliary routes and may become inactive after chelation with faecal material.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch

Dextrose

Magnesium stearate

Calcium carbonate

Sucrose

6.2 Incompatibilities

Not to mix with other medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sales: 3 years.

6.4 Special precautions for storage

Store bellow 30℃, keep in dry place, seal and protect from light.

6.5 Nature and composition of immediate packaging

Pack size: Bubble cap packaging, with aluminum foil for medicine as the backing material, with PVC as blister, and bolus will be sealed inside the blister, and then packaged in packing box. 5 boluses per blister, 11 blister per box.

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

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

7. MARKETING AUTHORIZATION HOLDER

Company name: Hebei New Century Pharmaceutical Co., Ltd.

Telephone: +86-311-85096552

Telefax: +86-311-85096552

E-Mail: lvliying100@hotmail.com.

8. MARKETING AUTHORIZATION NUMBER(S)

GMP number: (2022) Veterinary drug GMP No.03034

9. DATE OF REVISION OF THE TEXT

05.2023