SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Occrycetin Bolus 500 mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each tablet contains:

	mg
Oxytetracycline Hydrochloride	500

Excipient(s):

Tartrazine Lake (E102)	21
Sunset Yellow Lake (E110)	21

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
An orange tablet with a typical ovaloid bolus shape deeply scored on one face.

4. CLINICAL PARTICULARS

4.1 Target species

Calves.

4.2 Indications for use, specifying the target species

For use in the treatment of gastrointestinal infections in calves caused by both gram-positive and gram-negative pathogenic bacteria sensitive to oxytetracycline.

4.3 Contraindications

Do not use in calves with functional rumens.
Do not use in cases of known hypersensitivity.

4.4 Special warnings

None.

4.5 Special precautions for use

i. Special precautions for use in animals

None.

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

In the event of accidental ingestion, immediately flush mouth with water. Seek medical attention taking this warning to show your doctor.

In the event of contact with the eyes, flush with plenty of water. If irritation persists seek medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Occrycetin is of low toxicity and side effects are rarely encountered.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Oral: The bolus may be given either whole or crushed. Dosage must be determined by the severity of the case but in general the following dosage is recommended.

Calves: 1 bolus per 50 kg bodyweight twice daily. Treatment should be continued for approximately 5 days.

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

Oxytetracycline is of low toxicity and there is a wide safety margin at the recommended dose. On rare occasions overdosage may cause diarrhoea and overgrowth of yeasts and fungi. The medication should be withdrawn and appropriate treatment applied.

4.11 Withdrawal period(s)

Calves must not be slaughtered for human consumption during treatment. Calves may be slaughtered for human consumption only after 14 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Oxytetracycline is a broad-spectrum antibiotic of the tetracycline group. Although it is absorbed orally, it is excreted in the urine and faeces. At the recommended dosage, its pharmacological effect is limited to its antibiotic activity in the gastrointestinal tract.

ATCVet Code: QJ01AA06

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartrazine Lake (E102)
Sunset Yellow Lake (E110)
Lactose Monohydrate
Kaolin Light
Magnesium Stearate
Povidone K90
Sodium Starch Glycollate Type A

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4. Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A smoke grey polystyrene plastic box, with divisions separating 10 sets of 2 boluses with a green lid of low and high density polyethylene blend designed to slide along the length of the container.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4087

9. DATE OF FIRST AUTHORISATION

Date: 09 August 1991

10. DATE OF REVISION OF THE TEXT

Date: January 2014

APPROVED T. NASH **8 January 2014**