SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycare Tablets 100mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance(s) :

Oxytetracyline dihydrate	100mg

Excipient(s) :

Titanium dioxide (E171)	1.4mg
Tartrazine Lake 15002 (E102)	0.8mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
A yellow, sugar-coated, biconvex tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of dogs with bacterial infections sensitive to tetracycline therapy only. Soft tissue infections caused by Staphylococcus aureus or Streptococcus spp. have been shown to be highly sensitive. Respiratory infections caused by Bordetella bronchiseptica are also commonly sensitive.

4.3 Contraindications

Contraindicated for use in animals with hypersensitivity to any tetracycline.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

i. Special precautions for use in animals

Oxytetracycline is deposited in growing teeth and bones and may cause yellow discolouration. It also crosses the placenta. For this reason it is not recommended in late pregnancy or in young animals. Caution must be taken in treating animals with renal or hepatic dysfunction; in such cases it may be necessary to reduce dosage levels.

ii. Special precautions for the person administering the veterinary medicinal product to animals

If you know you are hypersensitive (allergic) to oxytetracycline, do not handle the product.
In the event of accidental ingestion, flush mouth with plenty of water and seek medical advice.
In the event of eye contact, flush thoroughly with clean, running water. If irritation persists seek medical attention.
Wash hands after use.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Prolonged use of antibiotics of all types may promote the overgrowth of non-susceptible organisms to that antibiotic. Where it occurs therapy should be discontinued and appropriate control of the organisms substituted.

4.7 Use during pregnancy, lactation or lay

Oxytetracycline crosses the placenta. The product should not be used in late pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

The product must not be given concurrently with milk or antacids.

4.9 Amount(s) to be administered and administration route

For oral administration
An initial dose of 50mg/kg bodyweight should be given, followed by subsequent doses of 25mg/kg every 12 hours for 5 days. To be taken by mouth at least one hour before or two hours after feeding.

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

Gastric lavage may be beneficial in the first hours after ingestion and milk will reduce absorption. Thereafter conservative treatment.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Oxytetracycline

ATC Vet Code: QJ01AA06

5.1 Pharmacodynamic properties

Antibiotic of the tetracycline group, with a broad spectrum of activity against Mycoplasma, Chlamydia and Rickettsia and a range of Gram-positive and Gram-negative bacteria. (Little activity against E. coli, Salmonella, Proteus and Pseudomonads.) Tetracyclines are bacteriostatic; bacterial sensitivity testing is advisable to preclude resistance in the target infecting bacteria.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coating
Tartrazine Lake 15002 (E102)
Titanium Dioxide (E171)
Sucrose
Talc
White Beeswax
Carnauba Wax
Glucose Monohydrate
Povidone
Liquid Paraffin
Sodium Starch Glycollate Type A
Maize Starch
Stearic Acid
Magnesium Stearate
IMS 74 OP

6.2 Incompatibilities

Aluminium, magnesium and calcium interfere with absorption of oxytetracycline; it must not be given concurrently with milk or antacids.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

A white, polypropylene tub with a low density polyethylene packing with a white, low density polyethylene cap (push fit), containing 1000 tablets.

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

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

Animalcare Ltd
10 Great North Way
York Business Park
Nether Poppleton
York
YO26 6RB

8. MARKETING AUTHORISATION NUMBER

Vm 10347 / 4002

9. DATE OF FIRST AUTHORISATION

Date: 22 June 1992

10. DATE OF REVISION OF THE TEXT

Date: June 2013

APPROVED T. NASH **3/07/13**