SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxycare 20 %w/v LA Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Oxytetracycline	20.0% w/v
(Equivalent to Oxytetracycline Dihydrate	21.60% w/v)

Excipients:

Sodium Formaldehyde Sulphoxylate Dihydrate	0.40 % w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A Clear amber solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

Oxycare 20/LA is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity. Blood levels persist for at least 4 days. After administration by the intramuscular route maximum blood levels are achieved after 4 to 8 hours making Oxycare 20/LA suitable for the treatment of acute infections. Oxytetracycline has been shown to be effective in vitro against the following bacterial species:
Bordetella bronchiseptica, Corynebacterium pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Haemophilus somnus, Pasteurella haemolytica, Pasteurella multocida, Salmonella dublin, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes and *Streptococcus uberis*.

Oxycare 20/LA is indicated in the treatment of:

- Atrophic rhinitis caused by *Bordetella bronchiseptica*, *Pasteurella haemolytica* and *Pasteurella multocida*;
- Navel/joint ill caused by *Corynebacterium pyogenes*, *E. coli*, and *Staphylococcus aureus*;
- Mastitis caused by *Corynebacterium pyogenes*, *E. coli, Staphylococcus aureus, Streptococcus agalactiae*, and *Streptococcus uberis*;
- Metritis caused by *E. coli* and *Streptococcus pyogenes*;
- Pasteurellosis and infections of the respiratory tract caused by *Pasteurella haemolytica* and *Pasteurella multocida*;
- Septicaemia caused by *Salmonella dublin* and *Streptococcus pyogenes*;
- Erysipelas caused by *Erysipelothrix rhusiopathiae.*

Oxycare 20/LA can also be used in the control of enzootic abortion in sheep.

4.3 Contra-indications

Not recommended for use in horses, dogs, cats.
Not for use in animals suffering from hepatic or renal damage.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

Do not dilute Oxycare 20 LA.
If concurrent treatment is administered, use a separate injection site.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possiable, thearpy should be based on local (regional, farm level) epidermiological information about susceptibility of the target bacteria.

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

Take care to avoid accidental self-injection.
Wash hands after use. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

4.6 Adverse reactions (frequency and seriousness)

Although the product is well tolerated, occasionally a slight local reaction of a transient nature has been observed.

4.7 Use during pregnancy, lactation or lay

The use of tetracycline during the period of tooth and bone development, including late pregnancy may lead to tooth discoloration, Oxycare 20/LA can be safely administered to lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. The product is recommended for a single administration only.

Maximum recommended dose at any one site:

Cattle	:		20ml
Pigs	:		10ml
Sheep	:		5ml
Piglets	:	1 day	0.2ml
		7 days	0.3ml
		14 days	0.4ml
		21 days	0.5ml
		Over 21 days	1.0 ml/10kg

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

No treatment specified.

4.11 Withdrawal period

Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 10 days from the last treatment. Milk for human consumption may be taken from sheep only after 7 days from the last treatment.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 31 days from the last treatment. Pigs may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 9 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials

ATC Vet Code: QJ01AA06

5.1 Pharmacodynamic properties

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 aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis. Oxycare 20/LA is specifically formulated to provide a rapid and prolonged action resulting in sustained antibacterial activity. Blood levels persist for at least 4 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate Dihydrate
Magnesium Oxide light,
Dimethylacetamide,
Disodium Edetate Dihydrate,
Ethanolamine (for pH adjustment),
Water for injection.

6.2 Incompatibilities

None Known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after the first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material
When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

6.5 Nature and composition of immediate packaging

Amber type II glass vials of 50 ml and 100 ml. Closed with nitrile rubber bungs with aluminium overseals.
Not all pack sizes may be marketed.

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

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4156

9. DATE OF FIRST AUTHORISATION

30th April 1998

10. DATE OF REVISION OF THE TEXT

October 2008

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