

Oxycare 20% w/v LA Solution for Injection

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

A sterile solution for injection containing oxytetracycline 20.00% w/v, 200 mg/ml, equivalent to oxytetracycline dihydrate 21.60% w/v, 216 mg/ml. Sodium formaldehyde sulphoxylate dihydrate (0.4%w/v)

INDICATION(S)

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

CONTRAINDICATIONS

Oxycare 20% w/v LA is not recommended for use in horses, dogs and cats.
Not for use in animals suffering from renal or hepatic damage.

ADVERSE REACTIONS

Although Oxycare 20% w/v LA is well tolerated, occasionally a slight reaction of a transient nature has been observed.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Cattle, Sheep, Pigs.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended dosage rate is 20mg/kg bodyweight (1ml per 10kg bodyweight) 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 1.0ml/10kg |

ADVICE ON CORRECT ADMINISTRATION

Do not dilute Oxycare 20% w/v LA.

If concurrent treatment is administered, use a separate injection site.

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.

SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Do not store above 25°C. 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. When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

SPECIAL WARNINGS

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

Operator Warnings:

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

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2008

OTHER INFORMATION

Package Quantities:

Multi-dose vials of 50ml and 100ml.

If stored as directed Oxycare 20% w/v LA can be expected to retain its potency for 2 years from the manufacturing date.

Marketing Authorisation Number:

Vm 02000/4156

POM-V

To be supplied only on veterinary prescription.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufactured by:

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

Distributed by:

Animalcare Ltd.
10 Great North Way
York, YO26 6RB

FOR ANIMAL TREATMENT ONLY