

enrocare[®] 100mg/ml Solution for Injection for Cattle and Pigs

1 ml of solution for injection contains 100mg of enrofloxacin and 30mg of butyl alcohol as antimicrobial preservative.

Presentation: 1 ml of solution for injection contains 100mg of enrofloxacin and 30mg of butyl alcohol as antimicrobial preservative. Enrocare 100mg/ml Solution for Injection is a clear, light yellow, sterile, aqueous solution.

Indications:

Cattle: Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. *pasteurellosis*, *mycoplasmosis*, *coli-bacillosis*, *coli-septicaemia* and *salmonellosis*) and secondary bacterial infections subsequent to viral conditions (e.g. viral pneumonia), where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice. Treatment of local signs (inflammation, milk quality and yield) associated with peracute/acute mastitis in lactating dairy cattle caused by *E. coli*, where herd history and previous sensitivity testing indicate enrofloxacin as the drug of choice.

Pigs, weighing more than 25kg: Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. *pasteurellosis*, *mycoplasmosis*, *coli-bacillosis*, and *salmonellosis*) and multifactorial diseases such as atrophic rhinitis and enzootic pneumonia, where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Contraindications: Do not use in cases of resistance against other fluoroquinolones, due to the potential for cross-resistance. Do not use for prophylaxis. Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Adverse Reactions: Local tissue reactions may occur at the injection site. Normal sterile precautions should be taken. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target Species: Cattle and Pigs weighing more than 25kg.

Dosage and Administration:

Cattle	<p>For respiratory and alimentary infections in cattle and secondary bacterial infections: administer by subcutaneous injection.</p> <ul style="list-style-type: none">• 2.5mg enrofloxacin per kg bodyweight (2.5ml per 100kg bodyweight) daily by subcutaneous injection for 3 days. This rate may be doubled to 5mg/kg bodyweight (5ml per 100kg) for 5 days for salmonellosis and complicated respiratory disease. <p>Not more than 10ml should be administered at any one subcutaneous injection site.</p> <p>For <i>E. coli</i> mastitis: administer by slow intravenous injection.</p> <ul style="list-style-type: none">• 5mg enrofloxacin per kg bodyweight (5ml per 100kg bodyweight) daily for 2 days.
Pigs (weighing more than 25kg)	<p>For respiratory and alimentary infections in pigs and secondary bacterial infections: administer by intramuscular injection.</p> <ul style="list-style-type: none">• 2.5mg enrofloxacin per kg bodyweight (2.5ml per 100kg bodyweight) daily by intramuscular injection for 3 days. This rate may be doubled to 5mg/kg bodyweight (5ml per 100kg) for 5 days for salmonellosis and complicated respiratory disease. <p>Not more than 2.5 ml should be administered at any one intramuscular injection site in store pigs or 5ml at any one intramuscular injection site in sows.</p>

The vial seal may be punctured up to a maximum of 25 times for the 100ml vials, or 50 times for the 250ml vials.

Advice on Correct Administration: Normal sterile precautions should be taken. To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

When the container is breached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Withdrawal Periods: **Cattle:** Subcutaneous use. Meat and offal: 10 days. Milk: 84 hours (7 milkings)
Cattle: Intravenous use. Meat and offal: 4 days. Milk: 72 hours (6 milkings)

Pigs: Intramuscular use. Meat and offal: 10 days

Storage Precautions: Keep out of the reach and sight of children. Do not store above 25°C. Do not freeze. Keep the vial in the outer carton in order to protect from light. Do not use after the expiry date stated on the label and carton after "EXP". Shelf-life after first opening the immediate packaging: 28 days

Special Warnings: Do not exceed the recommended dosage. In accidental overdose there is no antidote and treatment should be symptomatic.

Official and local antimicrobial policies should be taken into account when the product is used. Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Where possible, fluoroquinolones should only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

User Warnings: This product is an alkaline solution. Wash any splashes from skin and eyes immediately with water.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.

Do not eat, drink or smoke whilst using the product.

In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

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

Packaging Quantities: Vials of 100ml or 250ml. Not all pack sizes may be marketed.

Date on which the package leaflet was last approved February 2010.

Marketing Authorisation Holder:

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

Manufacturer for the batch release:

Produlab Pharma B.V., Forellenweg 16, 4941 SJ Raamsdonkveer, Netherlands

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To be supplied only on veterinary prescription.

For animal treatment only.

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Medicine