1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Primidoxine Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Trimethoprim	40.00 mg
Sulfadoxine	200.00 mg

Excipients

Chlorocresol (preservative)	1.00 mg
Sodium Formaldehyde Sulphoxylate	1.00 mg
N-Methylpyrrolidone	0.55 ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A pale yellow solution

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, Cattle, Pigs, Dogs and Cats

4.2 Indications for use, specifying the target species

Indicated in the treatment of acute, subacute and chronic conditions of bacterial origin. The therapeutic spectrum includes both gram-positive and gram-negative bacteria, including:

Streptococci Staphylococci Actinobacilli Actinomycae Salmonella Pasteurella Pneumococci Proteus Escherichia coli Corynebacteria Vibrio Bordetella Brucella Klebsiella Haemophilus

When susceptible organisms are present, the product may be effective for the treatment of alimentary tract infections, respiratory tract infections, urogenital tract infections, skin and wound infections and eye and ear infections.

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substances.
Do not administer to animals with liver parenchymal damage or blood dyscrasias. Do not use intraperitoneally

4.4 Special warnings for each target species

Do not administer to horses exhibiting drug-induced cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents

4.5 Special precautions for use Special precautions for use in animals

Administer only by routes recommended for each target species. Extreme caution must be exercised when the intravenous route of administration is being used. Adequate drinking water should be available during the therapeutic effect of the product.

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.

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

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic shock has been observed on rare occasions following administration of potentiated sulphonamide preparations mostly after intravenous injection. For intravenous administration the product should be warmed to body temperature and injected slowly over as long a period as is reasonably practical. At the first sign of intolerance the injection should be interrupted and shock treatment initiated. The intravenous route in the horse should only be used if therapeutically justified.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in Horses, Cattle, Pigs, Dogs and Cats during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

Administer intramuscularly or by slow intravenous injection to cattle and pigs at a dose rate of 1 ml of product per 16 kg bodyweight.

Administer by slow intravenous injection only to horses at a dose rate of 1 ml per 16 kg bodyweight.
Administer by subcutaneous injection only to dogs and cats at a dose rate of 1 ml per 8 kg bodyweight. Treat until 2 days after clinical signs resolve up to a maximum of 5 days.
Injections should not be given by routes other than those recommended.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

None

4.11 Withdrawal period(s)

Milk intended for human consumption may only be taken from 48 hours (that is at the 4th milking in cows milked twice daily) after the last treatment. Cattle and pigs intended for human consumption may only be slaughtered from 10 days after the last treatment. Horses intended for human consumption may only be slaughtered from 6 months after the last treatment

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, combinations of sulphonamides and trimethoprim ATCvet Code: QJ01EW13

5.1 Pharmacodynamic properties

Sulfadoxine is a member of the Sulphonamide group of antibiotics, and acts against bacteria by substitution of and competition for PABA, interfering in the synthesis of folic acid, which is required for DNA production and thereby bacterial cell replication. Trimethoprim inhibits the enzyme dihydrofolate reductase which converts dihydrofolic acid into tetrahydrafolic acid. Both antibiotics act together synergistically with a double blockade mode of action. The combination is bactericidal inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate
Chlorocresol
Monoethanolamine
Disodium Edetate
N-Methylpyrrolidone
Water for Injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years. Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Protect from light.
Crystallisation of the product at low temperatures can be reversed by gently warming.

6.5 Nature and composition of immediate packaging

The product is packaged into Amber Type II glass vials of 50 ml and 100ml sealed with bromobutyl bungs and aluminium overseals.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate
Monaghan Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/022/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 October 1989

Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT