Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroprim Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Active substance:

Trimethoprim 6.67% w/w
Sulfadiazine 33.33% w/w

Excipients:

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Granules.
White to off-white granules

4 CLINICAL PARTICULARS

4.1 Target Species

Horse.

4.2 Indications for use, specifying the target species

Noroprim Granules are recommended in the treatment of infections in horses caused by organisms sensitive to trimethoprim/sulfadiazine combinations. In vitro, Noroprim Granules are effective against *Escherichia coli, Corynebacterium equi, Staphylococcusspp*. and *Streptococcus spp.*.
When susceptible organisms are present Noroprim Granules may be effective in treating the following conditions:
respiratory tract infections including pneumonia, pleurisy, strangles, wounds, septicaemia and general infections.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.Do not use in animals with severe liver or kidney parenchymal damage or blood dyscrasias.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.
Whenever possible the product should only be used on the basis of susceptibility testing

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Avoid inhalation and direct contact with skin. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

The use of trimethoprim-sulfadiazine combinations during pregnancy and lactation has not been shown to cause any adverse effects or foetal abnormalities.

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

For oral administration by addition to feeds. The recommended dose is 30 mg of combined active product per kg bodyweight daily, (5 mg trimethoprim and 25 mg sulfadiazine per kg). Treatment should be continued for up to 5 days or until 2 days after symptoms have resolved.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under-dosing.

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

Not applicable.

4.11 Withdrawal period(s)

Horses may only be slaughtered for human consumption after 28 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01EW10
Pharmacotherapeutic Group: Antibacterials for systemic use

5.1 Pharmacodynamic properties

The trimethoprim-sulfadiazine combination derives its activity from the fact that the drugs act together with a unique double blockade of action. Each drug inhibits a different step in the biosynthetic pathways used by micro-organisms in the synthesis of reduced folate co-factors. Sulfadiazine inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim greatly potentiates the antimicrobial activity of sulphonamides both *in vitro* and *in vivo*, resulting in a synergistic effect. The combination presents a broad spectrum of antibacterial activity against Gram-positive and Gram-negative bacteria. In vitro the product is effective against *Escherichia coli*, *Corynebacterium equi*, Staphylococci and *Streptococcus* spp.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Sodium Starch Glycolate
Lactose

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Any unused drug remaining in opened sachets after the last treatment should be discarded.

6.4 Special precautions for storage

Do not store above 25oC.

6.5 Nature and composition of immediate packaging

Aluminium foil sachets containing white to off-white granules.

Cartons of 10 sachets, each sachet containing 37.5 g of product.
Dosing device: 15 g scoop.

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

Unused product and part used sachets should either be returned to the supplier for disposal or be disposed of in accordance with any guidance from an appropriate waste regulation authority.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/037/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 March 1993
Date of last renewal: 23 January 2009

10 DATE OF REVISION OF THE TEXT

January 2019