Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duofast Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 8g syringe contains 40mg Trimethoprim and 200mg Sulphadiazine.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary Suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating cattle.

4.2 Indications for use, specifying the target species

Duofast is an intramammary suspension for the broad spectrum treatment of clinical mastitis in lactating cattle caused by organisms sensitive to the Trimethoprim/Sulphadiazine combination.

In vitro Duofast is effective against gram-positive and gram-negative bacteria including *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis* and other streptococcal species, staphylococcal spp., *Corynebacterium* spp., *Escherichia coli* and other gram-negative bacteria.

Clinically, Duofast has been shown to be effective in the routine treatment of mastitis in lactating cows. Duofast exerts a bactericidal activity at concentrations attained in the udder

4.3 Contraindications

Do not use in cattle with known sulphonamide sensitivity, with hepatic damage or with blood dyscrasias.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

Wash hands immediately after use.

In the event of spillage onto skin, wash the affected area immediately.

If you are known to be sensitised to sulphonamides avoid contact with the product.

4.6 Adverse reactions (frequency and seriousness)

In rare cases hypersensitivity reaction may occur.

4.7 Use during pregnancy, lactation or lay

Duofast is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For intramammary administration.

The contents of one syringe should be infused into each effected quarter via the teat canal, immediately after milking, at 12 hour intervals for up to three consecutive milkings.

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

None known.

4.11 Withdrawal period(s)

Edible tissues from slaughtered animal: 5 days
Milk for human consumption must not be taken from a cow during treatment.
Milk for human consumption may only be taken from 2 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Duofast contains trimethoprim and sulphadiazine as the active ingredients which act with a unique "double-blockade" mode of action. Each component disrupts a different vital link in the metabolic chain used by susceptible bacteria to make nucleic acids and proteins.

Sulphadiazine inhibits the incorporation of p-amino benzoic (PABA) acid into dihydrofolic acid. Sulphadiazine specifically competes with PABA for the enzyme dihydropteroate synthetase.

Trimethoprim selectively inhibits the enzyme dihydrofolate reductase thereby preventing the conversion of dihydrofolic acid into tetrahydrofolic acid, this sequential enzymatic blockage resulting in a synergistic effect and enhanced activity at the site of infection when the two compounds are present.
Thus in vitro trimethoprim greatly potentiates the antimicrobial activity of sulphonamides.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated Castor Oil
Arachis Oil

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

The shelf-life expiry date of Duofast should not exceed 2 years from the date of manufacture.

6.4 Special precautions for storage

Store below 25^0C.

6.5 Nature and composition of immediate packaging

Intramammary polyethylene syringe, polyethylene plunger, polyethylene cap. The product is supplied in cartons of 24 (8 g) syringe and plastic boxes of 120 (8 g) syringes.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 February 1999
Last date of renewal: 05 February 2004

10 DATE OF REVISION OF THE TEXT

January 2019