1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duofast Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 8 g syringe contains:

Active substances:

Trimethoprim	40 mg
Sulphadiazine	200 mg

Qualitative composition of excipients and other constituents
Hydrogenated Castor Oil
Arachis Oil

A cream stable intramammary suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Lactating cattle.

3.2 Indications for use for each target species

The veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product has been shown to be effective in the routine treatment of mastitis in lactating cows. The veterinary medicinal product exerts a bactericidal activity at concentrations attained in the udder.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precaution(s) for use in the target species.

Not applicable.

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

Wash hands immediately after use.
In case of accidental spillage onto skin, wash the affected area immediately.
People with known hypersensitivity to sulphonamides should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

The veterinary medicinal product should not enter water courses as trimethoprim and sulphadiazine may be dangerous for fish and other aquatic organisms.

3.6 Adverse events

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay
Pregnancy:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction
None known.

3.9 Administration route and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 5 days.
Milk: 2 days.

Milk for human consumption must not be taken from a cow during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJS1E

4.2 Pharmacodynamics

The veterinary medicinal product 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf-life

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

5.3 Special precautions for storage

Store below 25^0C.

5.4 Nature and composition of immediate packaging

Immediate packaging:
- Intramammary polyethylene syringe, polyethylene plunger, polyethylene cap.

Outer packaging and sales presentations:
- cartons of 24 (8 g) syringe
- plastic boxes of 120 (8 g) syringes.

Not all pack sizes may be marketed.

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

The veterinary medicinal product should not enter water courses as trimethoprim and sulphadiazine may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/003/001

8. DATE OF FIRST AUTHORISATION

05/02/1999

9. DATE OF REVISION OF THE TEXT

22/05/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).