ERYTHRO FZ POWDER

(Erythromycin & Furazolidone)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ERYTHRO FZ POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Kg Contains:
Erythromycin ……..… 60gm
Furazolidone …… 30gm

3. PHARMACEUTICAL FORM

Oral Powder

4. CLINICAL INFORMATION

4.1. Target species

Poultry.

4.2. Indications for use specifying the target species

For metaphylaxis (in flocks where the diagnosis has been confirmed) and treatment of the following infections caused by microorganisms sensitive to erythromycin: For metaphylaxis (in flocks where the diagnosis has been confirmed) and treatment of the following infections caused by microorganisms sensitive to erythromycin: Chickens: Chronic Respiratory Disease (CRD), infectious coryza, infectious synovitis, pasteurellosis, mycoplasmosis, staphylococcal and streptococcal infections. Turkeys: Aerosaculitis, runny nose, pasteurellosis, infectious synovitis, staphylococcal and streptococcal infections.

4.3. Contraindications

Do not use in cases of **hypersensitivity** to the active substance or to any of the excipients.

4.4. Special warnings for each target species

Not Reported.

4.5. Special precautions for use

Special precautions for safe use in the target species:

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 epidemiological information (at the regional, farm level) regarding the susceptibility of the target bacteria. Official, national and regional antimicrobial policies must be taken into consideration when using the product.

Use of the product outside the instructions in the SPC (Summary of Product Characteristics) leads to an increase in the prevalence of resistance to the active substance and may determine a decrease in the efficacy of treatments with antimicrobials from the tetracycline group due to cross-resistance.

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

Avoid contact of the product with the eyes and skin. In case of allergies caused by contact with the skin or eyes, immediately seek medical advice and present the product leaflet or the label to the doctor. Persons with known hypersensitivity to any of the components of the product should avoid contact with it. Precautions must be taken to avoid exposure when handling the product or preparing the medicated solution. Wear personal protective equipment consisting of a dust mask, goggles, and protective gloves. Wash hands after use

Special precautions for environmental protection:

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

None at the recommended dose

4.7. Use during pregnancy and lactation or lay

Not applicable.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

Macrolides and lincosamides should not be combined because they compete for the same binding site (50S ribosomal subunit of sensitive bacteria). Erythromycin increases the activity of warfarin and may decrease the level of corticosteroids

4.9. Dosage and administration route

For oral administration, in drinking water. Erythromycin is generally administered to poultry at a dose of 300-500 mg per liter of drinking water. Metaphylaxis (in flocks where the diagnosis has been confirmed): 4-6 g product per 1 liter of drinking water, for 3 consecutive days. Treatment: 8-10 g product per 1 liter of drinking water, for 4-5 consecutive days. The preparation of medicated water must ensure a sufficient quantity of medication is consumed within the next 24 hours. Any leftover unused medicated water must be discarded after 24 hours and fresh medicated water prepared for the next 24 hours. The veterinary medicinal product must be added to the drinking water by continuous mixing until the product is completely dissolved. No other sources of water apart from the medicated water should be available during the treatment period.

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

No data is available.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Not Applicable.

4.12. Withdrawal period:

Meat and offal: 24 hours.
Use is not authorised in poultry that produce eggs for human consumption..

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial agents for systemic use, macrolides
Veterinary Anatomical-Therapeutic Code: **QJ01FA01**

5.1. Pharmacodynamics properties

Erythromycin is a bacteriostatic antimicrobial belonging to the macrolide group. They inhibit protein synthesis by binding to the 50S ribosomal subunit of susceptible bacteria. It is active against Gram-positive bacteria, especially staphylococci, streptococci, and enterococci. In addition, it is active against Gram-negative bacteria such as Haemophilus spp., Pasteurella spp., and Neisseria spp. It is also active against mycoplasma, chlamydia, and rickettsia
Furazolidone: It is a nitrofuran antibacterial agent that is microbicidal against a broad spectrum of bacteria and protozoa.
Its action involves the enzymatic reduction of its nitro group inside the microbial cell, generating reactive intermediates.
These intermediates damage bacterial DNA, inhibiting replication and transcription, and also interfere with other cellular components.

5.2. Pharmacokinetic information

Erythromycin is absorbed after oral administration in the upper part of the small intestine. Several factors can influence erythromycin bioavailability, including the type of salt, dosage form, degradation in the gastrointestinal tract, food present in the stomach, and gastric emptying time. Both erythromycin base and stearate are susceptible to acid degradation and are therefore frequently used with enteric coating for protection. Both the ethylsuccinate form and the estolate form are dissociated in the intestine and then absorbed. Erythromycin is widely distributed throughout the body and into all fluids and tissues, including the prostate, macrophages, and leukocytes. Low levels can be detected in the cerebrospinal fluid
Furazolidone is rapidly and extensively absorbed after oral administration and undergoes extensive metabolism.
The primary metabolic pathway involves nitro-reduction to the aminofuran derivative, with key metabolites including 3-amino-2-oxazolidone (AOZ).
It is rapidly eliminated, but its metabolite AOZ can form stable protein-bound residues, which is a major concern in food animals.

6. PHARMACEUTICAL INFORMATION

6.1 Excipients

Cinnamon flavour
Amaranth (colouring agent FD&C Red No. 2)
Sodium Lauryl Sulphate
Sodium Citrate
Granulated Sugar

6.2 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: 2 years.
Shelf life after dilution or reconstitution according to instructions: 24 hours.

6.4. Special precautions for storage

Store below 25°C in a dry place.
Do not store in the refrigerator or freezer.
Protect from light and moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

250 gm & 2.5 kg

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 006303

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 09-03-1982

10. DATE OF REVISION OF THE TEXT

17-02-2025