DI-GONE ORAL POWDER

(Neomycin Sulphate, Streptomycin Sulphate, Sulfaguanidine, Kaolin, Pectin, Bismuth Subnitrate, and Vitamin A Acetate.)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

DI-GONE ORAL POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Neomycin Sulphate ……. 33.33mg
Streptomycin Sulphate …… 33.33mg
Sulfaguanidine …….. 333.33mg
Kaolin ……333.33mg
Pectin ……. 33.33mg
Bismuth Subnitrate …….. 166.67mg
Vitamin A Acetate …… 6666.67 IU

3. PHARMACEUTICAL FORM

Oral Powder

4. CLINICAL INFORMATION

4.1. Target species

Large Animals, Calves, Sheep & Goats.

4.2. Indications for use specifying the target species

For the treatment of non-specific inflammatory diseases of the digestive tract - diarrhea of various origins with and without putrefactive processes; tympani and gas colic; poisoning.

4.3. Contraindications

None.

4.4. Special warnings for each target species

Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, treatment should be based on local (regional and farm level) epidemiological information on the susceptibility of the target bacteria and official and national antimicrobial policies should be taken into account.

4.5. Special precautions for use

Not Applicable.

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

People with known hypersensitivity to the active substances should avoid contact with the veterinary medicinal product.
Avoid contact with eyes, skin, and mucous membranes.
Wash hands thoroughly after handling the product.
Keep out of reach of children.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

None known.

4.7. Use during pregnancy and lactation or lay

Can be used during pregnancy and/or lactation

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

Do not administer orally simultaneously with absorbable chemotherapeutic agents, as their absorption is inhibited.

4.9. Dosage and administration route

Large Animals: Give an initial dose of 48 gm, followed by half of the initial dose, twice daily for 3–5 days. **Calves, Sheep, and Goats:** Give an initial dose of 12 gm, followed by half of the initial dose, twice daily for 3–5 days.

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

The administration of the product to calves, Sheep and Goat doses three times the recommended daily dose for 7 days did not cause adverse reactions in treated animals.

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

Any person intending to manufacture, import, possess, distribute, sell, supply or use this veterinary medicinal product must first consult the competent authorities of the Member State concerned on the vaccination policies in force, as these activities may be prohibited in a Member State on the whole or part of its territory, in compliance with national legislation.

4.12. Withdrawal period:

Calves: Meat and offal: 12 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combinations of Aminoglycoside antibiotic, Sulfonamide antibiotic, Antidiarrheal, Antacid and protectant, Vitamin supplement

5.1. Pharmacodynamics properties

Di-Gone Oral powder is a combined product containing, Neomycin Sulphate, Streptomycin Sulphate, Sulfaguanidine, Kaolin, Pectin, Bismuth Subnitrate, and Vitamin A Acetate, which determines the pharmacological action of the dosage form, which has antiseptic, astringent, antiphlogistic, antispasmodic, adsorbent, antitoxic and protective effects
Sulfaguanidine is a chemotherapeutic agent from the group of limitedly absorbable sulfonamides and acts primarily in the digestive tract. It acts bacteriostatically, and in high doses bactericidally against Gram-positive and Gram-negative cocci, clostridia, coli bacteria, salmonella, vibrios, coccidia, etc.
Bismuth subnitrate is an inorganic salt of bismuth with a protective effect, which is expressed in the creation of a coating on the gastrointestinal epithelium, thus protecting it from irritation and erosion caused by potentially harmful substances.
Pectin belongs to the group of protective and adsorbing agents. Its pharmacodynamic effect on the gastric and intestinal mucosa includes adsorption of hydrogen cations, pepsin and bile acids and the formation of a protective pectin gel covering the mucosa.
Neomycin Sulphate: An aminoglycoside antibiotic that inhibits protein synthesis in bacteria by binding to the 30S ribosomal subunit.
Streptomycin Sulphate: An aminoglycoside antibiotic that inhibits protein synthesis in bacteria by binding to the 30S ribosomal subunit
Kaolin: An adsorbent that absorbs fluids and toxins in the gastrointestinal tract, providing relief from diarrhea.
Vitamin A Acetate: A fat-soluble vitamin essential for vision, immune function, and cell growth and differentiation.

5.2 Pharmacokinetic information

Sulfaguanidine is absorbed to a limited extent from the digestive tract of animals, but relatively better than other representatives of the group of poorly absorbable sulfonamides, by passive diffusion. It is retained in the intestine, but a part of it is absorbed, especially in cases of constipation or dehydration. This provides some advantages in infections localized in the mucosa of the digestive tract. Sulfaguanidine is eliminated mainly via the feces. Absorbed sulfaguanidine is excreted acetylated via the urinary tract.
Bismuth Subnitrate: The absorption of bismuth from bismuth subnitrate after oral administration is very poor, as may increase when administered simultaneously with citrate and products containing sulfhydryl groups. The bioavailability of bismuth and bismuth subnitrate is very low (well below 1%). The highest concentrations of bismuth are found in the kidneys, lower in the lungs, spleen, liver, brain, bones and muscles. Bismuth is retained in the kidneys for a longer time compared to other organs. Bismuth not absorbed from the digestive tract is eliminated in the feces, and the absorbed is eliminated from the body in the urine and feces (including bile).

Pectin is not absorbed from the gastrointestinal tract after oral administration.
Neomycin Sulphate: Poorly absorbed from the gastrointestinal tract in animals. Primarily acts locally within the gut. Systemic absorption, though minimal, can occur, especially with damaged intestinal mucosa. Excreted mainly unchanged in feces.
Streptomycin Sulphate: Poorly absorbed from the GI tract. Given primarily by injection (intramuscular or subcutaneous) for systemic effects. Distribution is primarily extracellular. Eliminated largely unchanged by renal filtration.
Kaolin: Not absorbed systemically. Remains in the GI tract and is eliminated in the feces.
Vitamin A Acetate: Absorbed from the GI tract, with absorption enhanced by the presence of fats. Stored primarily in the liver. Metabolized and excreted via the bile and feces

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

Do not administer orally simultaneously with absorbable chemotherapeutic agents, as their absorption is inhibited.

6.2. Shelf life

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

6.2. 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.

6.3. Nature and composition of primary conditioning

Printed Aluminum Paper Foil
Packed Size: 12gm sachet

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.: 118613

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 27-12-2023

10. DATE OF REVISION OF THE TEXT

14-02-2025