

Dianox Injection

(Diminazine Aceturate & Antipyrine)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dianox Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:

Diminazine Aceturate.....	105 mg
Antipyrine.....	131 mg

3. PHARMACEUTICAL FORM

Injection solution.

4. CLINICAL PARTICULAR

4.1 Target species

Cattle, Sheep, Goats, Horses and dogs.

4.2 Therapeutic indications specified for each animal species

Treatment of trypanosomiasis, babesiosis (piroplasmosis) and mixed infections caused by trypanosomes and babesia in Cattle, Sheep, Goats, horses and dogs.

Dianox Injection is also intended for the control of processes associated with reduced immunity, in the case of temporary disappearance of ticks from the place of animal breeding or transportation from a tick-free area to a heavily infested area.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.

4.4 Special precautions for use in each target species

There is none

4.4 Special precautions for use

Special precautions for use in animals Do not administer more than 10 ml at the same injection site.

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

4.5 Adverse reactions (frequency and seriousness)

There are no known ones.

4.6 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only after a benefit/risk assessment by the responsible veterinarian.

4.7 Interaction with other veterinary medicinal products and other forms of interaction

They are not known.

4.8 Dosage and administration

For deep intramuscular administration.

Cattle & Horses: 10 ml /300 kg Body Weight.

Sheep & Goat: 0.3ml /10kg Body weight.

Dogs: 1 ml /22 kg body weight.

When administered to horses, it is necessary to divide the dose between 2 and 3 injection sites with an interval of 1 hour between injections to avoid a corresponding manifestation of colic.

If it is necessary to repeat the treatment, it can be done after 24 hours. A maximum of 3 treatments can be performed with an interval of 1 day.

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

Overdose may cause irritation at the injection site and colic in horses. Overdose up to 3 times may cause death of the animals.

Do not exceed the recommended dose.

4.10 Withdrawal period

Cattle Sheep & Goat: Meat: 21 Days

Horse & Dog: Not Applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dianox Injection is highly effective in the treatment of parasitic infections caused by blood protozoa such as Trypanosoma and Babesia in Cattle, Sheep, Goats, horses and dogs. Its activity against trypanosomes has been extensively studied. Its action is expressed in rapid and irreversible binding to DNA contained in the organelles of trypanosomes and selective blocking of DNA synthesis of the parasites.

Dianox Injection rapidly eliminates babesia from the blood when administered in therapeutic doses.

Blood parasites can persist in the blood for up to four days after treatment, indicating that the product suppresses the reproduction of the parasites, but does not destroy them, but reduces the severity of babesiosis and creates a state of preliminary immunity.

5.2 Pharmacokinetic properties

Absorption of Diminazine is rapid after intramuscular administration. Maximum concentrations are reached within 1 hour after administration in Cattle, Sheep, Goats, horses and after 3 hours in dogs.

After intramuscular administration, antipyrine shows rapid absorption - 6.6 minutes, resulting in a C_{max} of 1849 ng/ml with a T_{max} of 20 minutes. This is followed by a rapid distribution phase (T_{1/2} 21.6 minutes). The estimated elimination half-life (T_{1/2}) was determined to be 5.31 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 Shelf life

Shelf life of the finished veterinary medicinal product: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.2. Special storage conditions for the product

Store below 30°C. Protect from heat and light.
Keep out of reach of children.

6.3 Nature and composition of immediate packaging

10ml glass vial, with a rubber stopper and aluminium flip off-seals.
50ml glass vial, with a rubber stopper and aluminium flip off-seals.
100ml glass vial, with a rubber stopper and aluminium flip off-seals.

6.4 Special precautions for the disposal of unused product or waste materials derived from it

Any unused veterinary medicinal product or waste material should be disposed of in accordance with local requirements.

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.: 072674

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 29-08-2011

10. DATE OF REVISION OF THE TEXT

05-06-2024