VALONE INJECTION

(Buparvaquone)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Valone Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Buparvaquone ……..…50.00 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep & Buffalos

4.2. Indications for use specifying the target species

Treatment of bovine theileriosis caused by different types of theileria T.Parva, T.Annulata, T.Orientalis. It is active against both the Schizonts & Piroplasms stages of Theileria and may be used during the incubation period of the disease or when clinical signs are apparent.

4.3. Contraindications

Should never be given by intravenous or subcutaneous injection.

4.4. Special warnings for each target species

Cattle:
Pregnancy: Buparvaquone should not be used in pregnant cattle as it may cause harm to the unborn calf.
Lactation: Buparvaquone should not be used in lactating cattle as it may pass into the milk and harm the calf.
Concurrent illness: Buparvaquone may not be effective in cattle with severe concurrent illness, such as pneumonia or mastitis.

Sheep:
Pregnancy: Buparvaquone should not be used in pregnant sheep as it may cause harm to the unborn lamb.
Lactation: Buparvaquone should not be used in lactating sheep as it may pass into the milk and harm the lamb.
Concurrent illness: Buparvaquone may not be effective in sheep with severe concurrent illness, such as pneumonia or mastitis.

4.5. Special precautions for use

Special precautions for use in animals:

Buparvaquone should not be used in pregnant or lactating animals as it may harm the fetus or offspring.
Use with caution in animals with pre-existing liver or kidney dysfunction as Buparvaquone is primarily metabolized in the liver and excreted by the kidneys.
Do not use in animals with known hypersensitivity to Buparvaquone or any component of the formulation
May not be effective in animals with severe concurrent illnesses
Repeated use may lead to parasite resistance.

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)

Common adverse reactions associated with Buparvaquone Injection may include transient local irritation or inflammation at the injection site, gastrointestinal upset (such as vomiting or diarrhea), and allergic reactions (such as itching, hives, or swelling). Rare but serious adverse reactions may include anaphylaxis or other severe hypersensitivity reactions.

4.7. Use during pregnancy and lactation or lay

It is stated that it is detected in milk 35 days after the drug is applied
It is not recommended to be used with vaccines and in pregnant animals

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

There are no known drug interactions with Buparvaquone Injection. However, caution should be exercised when administering other medications concurrently, as the safety and efficacy of concurrent therapy have not been established.

4.9. Dosage and administration route

Cattle application:
For intramuscular injection into the neck muscles.
Dose rates/directions for use:
A single dose of 1ml per 20kg bodyweight. (2.5mg Buparvaquone/ kg bodyweight).
In severe and advanced cases, a second treatment may be required at 48-72 hrs after the initial injection at the same dose rate.
Avoid wet or dirty areas of the skin.
No more than 10ml should be injected into a single site.

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

Data not available. Do not exceed recommended doses

4.11. Withdrawal period:

Meat: 42 days
Milk: 48 Hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoal Group
ATCvet code: **QP51EX03.**

5.1. Pharmacodynamic properties

Buparvaquone's mechanism of action centers around inhibiting the parasite's mitochondrial electron transport chain, specifically at the cytochrome bc1 complex.
This disruption of energy production ultimately leads to the parasite's death. This targeted action translates into several key pharmacodynamic effects. Buparvaquone demonstrates potent antiprotozoal activity, proving highly effective against various *Theileria* species, notably *Theileria parva* and *Theileria annulata*. Following administration, the drug exhibits a rapid onset of action, quickly absorbing and distributing throughout the body to achieve therapeutic concentrations at the infection site. Furthermore, its relatively long half-life contributes to a long-lasting effect, sustaining antiprotozoal activity and minimizing the need for frequent dosing. Beyond its direct antiparasitic impact, buparvaquone may also possess immunomodulatory properties, potentially enhancing the host's immune response against the invading parasite.

5.2. Pharmacokinetic information

Following intramuscular administration, buparvaquone is rapidly absorbed, reaching peak plasma concentrations within 1-3 hours. It is then widely distributed throughout the body, including the brain and cerebrospinal fluid, demonstrating a high volume of distribution which indicates extensive penetration into tissues and organs. Metabolism of buparvaquone primarily occurs in the liver, though the specific metabolites remain poorly characterized. The primary route of excretion is via the feces, with a small portion eliminated in the urine.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

Incompatibilities of Buparvaquone Injection may be limited in available veterinary

6.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use immediately, do not store.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use within 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.
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

Cardboard box with glass injection vial (s).
Glass vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.

Pack sizes: 20ml

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.: 117159

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 21-07-2023

10. DATE OF REVISION OF THE TEXT

29-01-2025