

# **STROX-34% INJECTION**

## *(Nitroxynil)*

### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### **1 NAME OF THE VETERINARY MEDICINAL PRODUCT**

STROX-34% INJECTION.

#### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

Nitroxynil.....340mg

#### **3. PHARMACEUTICAL FORM**

Solution for injection.

#### **4. CLINICAL INFORMATION**

##### **4.1. Target species**

Sheep and Cattle.

##### **4.2. Indications for use specifying the target species**

The product is indicated for the treatment of fascioliasis (infestation of mature and immature *Fasciola hepatica*) in cattle and sheep. It is also effective, at the recommended dose rate, against adult and larval infestations of *Haemonchus contortus* in cattle and sheep and *Haemonchus placei*, *Oesophagostomum radiatum* and *Bunostomum phlebotomum* in cattle. However, Strox-34% should not be regarded or used as a broad spectrum anthelmintic.

##### **4.3. Contraindications**

Do not use in animals with known hypersensitivity to the active ingredient.

Do not exceed the stated dose.

Do not use in dogs as fatalities have been reported.

##### **4.4. Special warnings for each target species**

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.

- Underdosing which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

#### **4.5. Special precautions for use**

Special precautions for safe use in the target species:

Ensure the injection does not enter subcutaneous muscle.

Ewes in advanced pregnancy and not intended to produce milk for human consumption should be driven, handled and dosed carefully.

Estimate the weight of the sheep carefully and use injection equipment calibrated to accurately deliver the calculated dose.

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

Strox-34% solution stains and care should be taken not to spill it, especially on the fleece of sheep. Wash splashes from skin and eyes immediately. Wear suitable gloves to avoid staining the skin.

#### **4.6. Adverse reactions (frequency and seriousness)**

Small swellings are occasionally observed at the injection site in cattle. These can be avoided by injecting the dose in two separate sites and massaging well to disperse the solution.

No systemic ill effects are to be expected when animals (including pregnant cows and ewes) are treated at normal dosage.

#### **4.7. Use during pregnancy and lactation or lay**

The product is safe for use during pregnancy.

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

No signs of incompatibility are to be expected if Strox-34% is administered to cattle or sheep concurrently with therapeutic doses of the following anthelmintics: levamisole and thia-bendazole, or with clostridial vaccine.

#### **4.9. Dosage and administration route**

Administer by subcutaneous injection.

The standard dosage is 10 mg nitroxynil per kilogram bodyweight.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible as overdosage may result in signs of toxicity; accuracy of the dosing device should be checked.

Sheep: 1.5 ml of Strox-34% Solution for Injection per 50 kg (1cwt) liveweight.

Liveweight (kg)	Dose (ml)
20	0.6
30	0.9
40	1.2
50	1.5
60	1.8
70	2.1
80	2.4
90	2.7
100	3

In outbreaks of fascioliasis each sheep in the flock should be injected immediately the presence of the disease is recognised, repeating treatment as necessary throughout the period when infestation is occurring, at intervals of not less than one month.

On farms with fluke-infested pastures, routine preventative dosing should be carried out at intervals of not less than one month, having regard for such factors as the past disease history of the farm, the frequency and severity of neighbouring outbreaks and regional forecasts of incidence.

Cattle: 1.5 ml of Strox-34% Solution for Injection per 50 kg (1cwt) liveweight.

Liveweight (kg)	Dose (ml)
100	3
200	6
300	9
400	12
500	15
600	18
700	21
800	24

Both infected and in-contact animals should be treated, treatment being repeated as considered necessary, though not more frequently than once per month. The treatment of cattle helps to reduce contamination of pastures on farms where fascioliasis is endemic or certain roundworm occurrence is evident.

The dosing tables are given as a guide. Cattle or sheep that fall between the weights listed must have their dose calculated appropriately.

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

In the event of accidental overdosage, the symptoms are pyrexia, rapid respiration and increased excitability. Patients should be kept cool, and dextrose saline should be administered intravenously.

#### **4.12. Withdrawal period:**

Cattle and sheep may be slaughtered for human consumption only after 60 days from the last treatment.

Not authorised for use in cattle and sheep producing milk for human consumption including during the dry period. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Anthelmintics, nitroxinil.

ATCvet code. **QP52AG08**

### **5.1. Pharmacodynamics properties**

The main pharmacological action of nitroxinil is fasciolicidal. The lethal action against *Fasciola hepatica* has been demonstrated in vitro and in vivo in laboratory animals, and in sheep and cattle. The mechanism of action is thought to be due to uncoupling of oxidative phosphorylation. Few other pharmacodynamic effects have been observed at therapeutic doses. Hyperpnoea and increased rectal temperature are seen at high doses, and near toxic doses cause an increase in blood pressure.

## 5.2. Pharmacokinetic information

The pharmacokinetics of nitroxynil in sheep and cattle are very similar. After subcutaneous injection of a single dose of 10 mg/kg peak plasma levels of 83.6 µg/ml are achieved at 9.3 hours in sheep, and peak plasma levels of 91.6 µg/ml are achieved at 13 hours in cattle. The plasma half-lives are 5 days and 8 days in sheep and cattle respectively. This slow rate of elimination is in accordance with the observed long duration of action of Strox-34% against fluke in sheep and cattle.

## 6. PHARMACEUTICAL INFORMATION

### 6.1 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

### 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 within 28 days, do not store.

### 6.2. 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.

### 6.3. Nature and composition of primary conditioning

Cardboard box with glass injection vial (s).  
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.  
Pack sizes: 10ml, 50ml & 100ml

### 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.: 119876

## 9. DATE OF FIRST AUTHORISATION

Date of Reg.: 23-01-2024

## 10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:



**NAWAN**  
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