Strox 34% Injection

(Nitroxynil)

سٹروکس ۳۴٪ انجکشن
(نٹروکسنل)
۱۰ ملی لیٹر

10ml

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Strox-34% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Nitroxynil 340 mg/ml
as N-ethylglucamine salt.

Excipients:
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Bright orange-red solution.

4 CLINICAL PARTICULARS

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 use in animals

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 veterinary medicinal 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, lactation or lay

The product is safe for use during pregnancy. See section 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

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 thiabendazole, or with clostridial vaccine.

4.9 Amounts to be administered 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% 340 mg/ml 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% 340 mg/ml 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.

4.11 Withdrawal period(s)

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 or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Anthelmintics, nitroxinil. ATCvet code: QP52AG08

5.1 Pharmacodynamic properties

The main pharmacological action of nitroxynil 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 particulars

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 PARTICULARS

6.1 List of excipients

Eglumine
Water for Injections

6.2 Major incompatibilities
Do not mix with any other veterinary medicinal product.

6.3 Shelf-life
Shelf-life of the veterinary medicinal product as packaged for sale: 3 years Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage
Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging
100 ml DIN bottles with chlorobutyl rubber stopper.
250 ml, 500ml and 1 litre containers of natural polypropylene with chlorobutyl rubber stopper.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products
Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

8 MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

MANUFACTURED BY:
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