SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trodax 34% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Nitroxynil 34.0% w/v
As N-ethylglucamine salt.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, orange-red solution.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle.

4.2 Indications for use, specifying the target species

Trodax 34% 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, Oesphagostomum radiatum* and *Bunostomum phlebotomum* in cattle. However, Trodax should not be regarded or used as a broad spectrum anthelmintic.

4.3 Contra-indications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in dogs as fatalities have been reported.
Do not exceed stated dose.

4.4 Special warnings for each target species

Do not retreat at intervals less than 60 days (cattle) or 49 days (sheep).

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 body weight, misadministration of the product, or lack of calibration of the dosing

device (if any).

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 test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

To date, no resistance to nitroxynil has been reported. The use of the product should be based on local (regional, farm) epidemiological information about susceptibility of trematodes and nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

(i) 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 handled and dosed carefully.
Estimate the weight of the sheep carefully and use injection equipment calibrated to accurately deliver the calculated dosage.

Trodax solution stains and care should be taken not to spill it, especially on the fleece of sheep.

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

Wear impermeable gloves to avoid staining the skin. Wash splashes from skin and eyes immediately. Obtain medical help if irritation persists.

In case of accidental or deliberate ingestion, wash out the mouth with water and obtain medical help.

Care must be taken to avoid accidental self-injection. Seek medical assistance in case of accidental injection.

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

This product is safe for use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

No signs of incompatibility are to be expected if Trodax is administered to cattle or sheep concurrently with therapeutic doses of levamisole or with clostridial vaccine.

4.9

Amounts to be administered and administration route

Administer by subcutaneous injection.
To ensure administration of a correct dose, body weight should be determined as accurately as possible as overdosage may result in signs of toxicity; accuracy of the dosing device should be checked.
The standard dosage is 10mg nitroxynil per kilogram bodyweight.

Sheep: 1.5ml of Trodax 34% per 50kg (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

On farms with fluke-infested pastures, routine dosing should be carried out at intervals of not less than 49 days (7 weeks), 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.
In outbreaks of acute fascioliasis advice on the best treatment should be sought from a veterinary surgeon.

Cattle: 1.5ml of Trodax 34% per 50kg (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 60 days. 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 periods

Cattle may be slaughtered for human consumption only after 60 days from the last treatment. Sheep may be slaughtered for human consumption only after 49 days from the last treatment.
Not authorised for use in cattle and sheep producing milk for human consumption including 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

ATC Vet 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 in 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 properties

The pharmacokinetics of nitroxynil in sheep and cattle are very similar. After subcutaneous injection of a single dose of 10mg/kg peak plasma levels of 83.6μg/ml are achieved at 9.3 hours in sheep, and plasma levels of 91.6μg/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 Trodax against fluke in sheep and cattle.

Nitroxynil is active against triclabendazole-resistant *Fasciola hepatica.*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

Do not dilute or mix with other compounds.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C, protect from light.
Once the container has been broached, the contents should be used within 28 days.
This product does not contain a preservative.
Avoid the introduction of contamination. Should any apparent growth or discoloration occur, the product should be discarded.

6.5 Nature and composition of immediate packaging

250ml, 500ml and 1 litre containers of natural polypropylene with chlorobutyl rubber stopper containing a bright orange-red solution. Each container is presented in a cardboard carton.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

08327/4187

9. DATE OF FIRST AUTHORISATION

12 September 2005

10. DATE OF REVISION OF THE TEXT

November 2018

Approved 29 November 2018