PARTICULARS TO APPEAR ON THE OUTER PACKAGE (2 X 500 ml carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trodax 34% w/v solution for injection for cattle and sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Containing 34% w/v nitroxynil (as N-ethylglucamine salt)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

2 x 500 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

For treatment of liver fluke disease (caused by infestations of mature and immature *Fasciola hepatica)* and certain roundworm infestations in cattle and sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration
By subcutaneous injection at a convenient site, taking normal aseptic precautions. In sheep this site should preferably be free from wool. Massage injection site after administration.

Dosage
The standard dosage is 10 mg nitroxynil per kg bodyweight: (1.5 ml of Trodax 34% solution per 50 kg liveweight).

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.

CATTLE
1.5 ml of Trodax 34% solution per 50 kg liveweight.

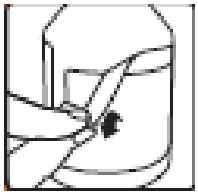
Liveweight (kg)	Dose (ml)	Approximate doses/pack	
		500ml	2 x 500ml
100	3	166	333
200	6	83	166
300	9	55	111
400	12	41	83
500	15	33	66
600	18	27	55
700	21	23	47
800	24	20	41

SHEEP
1.5 ml of Trodax 34% solution per 50 kg liveweight.

Liveweight (kg)	Dose (ml)	Approximate doses/pack	
		500ml	2 x 500ml
20	0.6	833	1666
30	0.9	555	1111
40	1.2	416	833
50	1.5	333	666
60	1.8	277	555
70	2.1	238	476
80	2.4	208	416
90	2.7	185	370
100	3	166	333

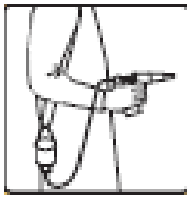
The dosing tables are given as a guide. Cattle or sheep that fall between the weights listed must have their dose calculated appropriately.

Convenience of the Trodax polypropylene pack



To release the hanging loop pull down label where indicated by arrows.

Remove plastic needle cover from the giving set Snap on the cap of the giving set over the head of the polypropylene pack.
Do not invert until the tube of the Trodax injector has been connected otherwise the contents will escape.



Trodax solution is sterile. Good hygiene is therefore essential when injecting animals.
The equipment should be kept in a clean sterile condition for this purpose.
Avoid the introduction of contamination during use.

8. WITHDRAWAL PERIOD

Not authorised for use in cattle and sheep producing milk for human consumption including during the dry period.

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

Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

Sheep may be slaughtered for human consumption only after 49 days from the last treatment.

Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications:
Do not use in dogs as fatalities have been reported.

User Warnings:
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.

Ewes in advanced pregnancy and not intended to produce milk for human consumption should be driven, handled and dosed carefully.
Trodax solution stains and care should be taken to avoid spilling it, especially on the fleece of sheep.

Do not dilute or mix with other compounds.
This product does not contain a preservative.

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

Once the container has been broached, the contents should be used within 28 days.

Do not store above 25°C. Protect from light. Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4187

17. MANUFACTURER'S BATCH NUMBER

Lot:

18. ADDITIONAL INFORMATION

See package leaflet for accompanying directions and user warnings.
This pack is ready for use with automatic syringes.
To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (250 ml carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trodax 34% w/v solution for injection for cattle and sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Containing 34% w/v nitroxynil (as N-ethylglucamine salt)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

For treatment of liver fluke disease (caused by infestations of mature and immature *Fasciola hepatica)* and certain roundworm infestations in cattle and sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration
By subcutaneous injection at a convenient site, taking normal aseptic precautions. In sheep this site should preferably be free from wool. Massage injection site after administration.

Dosage
The standard dosage is 10 mg nitroxynil per kg bodyweight: (1.5 ml of Trodax 34% solution per 50 kg liveweight).

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.

CATTLE
1.5 ml of Trodax 34% solution per 50 kg liveweight.

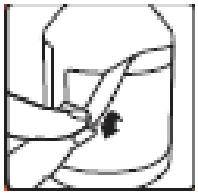
Liveweight (kg)	Dose (ml)	Approximate doses/pack
100	3	83
200	6	41
300	9	27
400	12	20
500	15	16
600	18	13
700	21	11
800	24	10

SHEEP
1.5 ml of Trodax 34% solution per 50 kg (1cwt) liveweight.

Liveweight (kg)	Dose (ml)	Approximate doses/pack
20	0.6	416
30	0.9	277
40	1.2	208
50	1.5	166
60	1.8	138
70	2.1	119
80	2.4	104
90	2.7	92
100	3	83

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

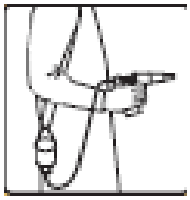
Convenience of the Trodax polypropylene pack



To release the hanging loop pull down label where indicated by arrows.

Remove plastic needle cover from the giving set Snap on the cap of the giving set over the head of the polypropylene pack.

Do not invert until the tube of the Trodax injector has been connected otherwise the contents will escape.



Trodax solution is sterile. Good hygiene is therefore essential when injecting animals.
The equipment should be kept in a clean sterile condition for this purpose.
Avoid the introduction of contamination during use.

8. WITHDRAWAL PERIOD

Not authorised for use in cattle and sheep producing milk for human consumption including during the dry period.

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

Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

Sheep may be slaughtered for human consumption only after 49 days from the last treatment.

Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications:
Do not use in dogs as fatalities have been reported.

User Warnings:
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.

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

Trodax solution stains and care should be taken to avoid spilling it, especially on the fleece of sheep.
Do not dilute or mix with other compounds.
This product does not contain a preservative.

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

Once the container has been broached, the contents should be used within 28 days.

Do not store above 25°C. Protect from light. Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4187

17. MANUFACTURER'S BATCH NUMBER

Lot:

18. ADDITIONAL INFORMATION

See package leaflet for accompanying directions and user warnings.
This pack is ready for use with automatic syringes.
To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (500 ml label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trodax 34% w/v solution for injection for cattle and sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Containing 34% w/v nitroxynil (as N-ethylglucamine salt)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

For treatment of liver fluke disease (caused by infestations of mature and immature *Fasciola hepatica)* and certain roundworm infestations in cattle and sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration
By subcutaneous injection.

Dosage: cattle and sheep
The standard dosage is 10 mg nitroxynil per kg bodyweight: (1.5 ml of Trodax 34% solution per 50 kg liveweight).

8. WITHDRAWAL PERIOD

Not authorised for use in cattle and sheep producing milk for human consumption including during the dry period.

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

Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

Sheep may be slaughtered for human consumption only after 49 days from the last treatment.

Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

See outer carton / package leaflet for accompanying directions and user warnings.

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

Once broached, use by:
Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See outer carton / package leaflet for accompanying directions and user warnings.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4187

17. MANUFACTURER'S BATCH NUMBER

Lot:

18. ADDITIONAL INFORMATION

To release hanging loop pull down label where indicated by arrows.
This pack is ready for use with automatic syringes.
To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (250 ml label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trodax 34% w/v solution for injection for cattle and sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Containing 34% w/v nitroxynil (as N-ethylglucamine salt)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

For treatment of liver fluke disease (caused by infestations of mature and immature *Fasciola hepatica)* and certain roundworm infestations in cattle and sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration
By subcutaneous injection.

Dosage: cattle and sheep
The standard dosage is 10 mg nitroxynil per kg bodyweight: (1.5 ml of Trodax 34% solution per 50 kg liveweight).

8. WITHDRAWAL PERIOD

Not authorised for use in cattle and sheep producing milk for human consumption including during the dry period.

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

Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

Sheep may be slaughtered for human consumption only after 49 days from the last treatment.

Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

See outer carton / package leaflet for accompanying directions and user warnings.

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

Once broached, use by:
Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See outer carton / package leaflet for accompanying directions and user warnings.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4187

17. MANUFACTURER'S BATCH NUMBER

Lot:

18. ADDITIONAL INFORMATION

To release hanging loop pull down label where indicated by arrows.
To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR: Trodax 34% w/v solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trodax 34% w/v solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Trodax is presented as a solution containing 34% w/v nitroxynil (as N-ethylglucamine salt). Each ml contains 340 mg of active ingredient.

4. INDICATION(S)

Trodax 34% solution is indicated for the treatment of fascioliasis (infestations 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, Trodax should not be regarded or used as a broad-spectrum anthelmintic.

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 of resistance to anthelmintics.

5. CONTRAINDICATIONS

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

No systemic ill-effects are to be expected when animals (including pregnant cows and ewes) are treated at normal dosage. However, the product is not permitted for use in animals producing milk for human consumption, including during the dry period, (see 'Withdrawal Periods' below).

Do not exceed the stated dose.
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 dosage.
Ensure the injection does not enter subcutaneous muscle.
Trodax solution stains and care should be taken not to spill it, especially on the fleece of sheep.

6. ADVERSE REACTIONS

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.
In the event of accidental overdosage, the symptoms are pyrexia, rapid respiration and increased excitability.
Patients should be kept cool, and dextrose saline solution should be administered intravenously. Do not retreat at intervals less than 60 days (cattle) or 49 days (sheep).

7. TARGET SPECIES

Cattle and sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administration and dosage
By subcutaneous injection.

Taking normal aseptic precautions the solution is injected subcutaneously at a convenient site. In sheep this site should preferably be free from wool. The injection site is then massaged gently to disperse the solution.

The standard dosage is 10 mg nitroxynil per kg bodyweight. (1.5 ml of Trodax / 50 kg bodyweight).

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Sheep
1.5 ml of Trodax 34% solution 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

On farms with fluke-infested pastures, routine preventive 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
1.5 ml of Trodax 34% solution 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

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

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 pasture on farms where fascioliasis is endemic or certain roundworm occurrence is evident.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid the introduction of contamination during use. Should any apparent growth or discoloration occur, the product should be discarded.

10. WITHDRAWAL PERIODS

Not authorised for use in cattle and sheep producing milk for human consumption including during the dry period.
Cattle may be slaughtered for human consumption only after 60 days from the last treatment. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.
Sheep may be slaughtered for human consumption only after 49 days from the last treatment. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Do not use after the stated expiry date.
Once the container has been broached, the contents should be used within 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the bottle should be discarded should be worked out. This discard date should be written in the space provided.
Keep container in outer carton. Do not store above 25°C, protect from light.

12. SPECIAL WARNING(S)

For Animal Treatment Only

User warnings:
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.
Do not dilute or mix with other compounds. 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. This product does not contain a preservative.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To be supplied only on veterinary prescription.

POM-VPS Vm 08327/4187

Approved 06 October 2020