

Take
control



of fluke
in cattle



Solantel[®]
Pour-On Solution for Cattle



**THE ONLY SINGLE ACTIVE
POUR-ON FLUKICIDE FOR CATTLE**




Norbrook[®]

What is Solantel® Pour-On?

Solantel Pour-On is the only single active flukicide available as a pour-on for cattle. It contains 200mg/ml closantel and offers targeted, effective fluke treatment as part of a strategic parasite control programme.

- ✓ Effective against adult and late immature liver fluke (from 7 weeks of age).
- ✓ Easy to use pour-on formulation is convenient for farmers and less invasive for cattle.
- ✓ Effective against triclabendazole-resistant liver fluke.
- ✓ Meat withdrawal period **63 days**.
- ✓ Suitable for use in dairy replacements up to the second half of pregnancy.



Efficacy data

The clinical efficacy of a single dose of Solantel Pour-On for the treatment of infections of *Fasciola hepatica*:

Adults (12 weeks)
≥99.8% ⁽¹⁾

Late immature (7 weeks)
≥98.3% ⁽¹⁾

Mean plasma concentration levels (ppm) peaked at 116hrs following administration of Solantel Pour-On.⁽²⁾

Handy dosing guide

Dose rate of **1ml per 10kg** bodyweight.

- Animals should be weighed and grouped according to bodyweight to avoid over or under dosing.
- Apply along the midline of the back in a narrow strip between the withers and the tail head.

| Body weight | Dose volume | No. of doses per pack | | |
|-------------|-------------|-----------------------|------|-----|
| | | 1L | 2.5L | 5L |
| 100kg | 10ml | 100 | 250 | 500 |
| 150kg | 15ml | 66 | 166 | 333 |
| 200kg | 20ml | 50 | 125 | 250 |
| 250kg | 25ml | 40 | 100 | 200 |
| 300kg | 30ml | 33 | 83 | 166 |
| 350kg | 35ml | 28 | 71 | 142 |
| 400kg | 40ml | 25 | 62 | 125 |
| 450kg | 45ml | 22 | 55 | 111 |
| 500kg | 50ml | 20 | 50 | 100 |
| 550kg | 55ml | 18 | 45 | 90 |
| 600kg | 60ml | 16 | 41 | 83 |

Closantel: the active of choice

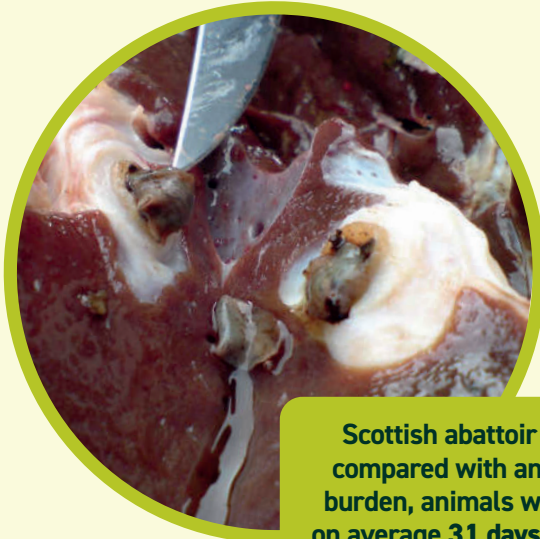
Solantel Pour-On contains closantel, a powerful, early-acting flukicide. Closantel belongs to the salicylanilides group of anthelmintics that binds extensively to plasma albumin. As a result, its activity is mainly directed against blood feeding internal parasites such as *Fasciola hepatica*.

Closantel is absorbed unchanged into the bloodstream, with limited distribution into other tissues. Unlike triclabendazole, closantel does not require metabolism by the liver to become active.

It is also believed to have a significant neurotoxic effect that causes spastic paralysis, resulting in the detachment of the fluke from its food source causing starvation. Exposure to closantel during fluke early development stages causes stunting and reduced the size of the treated flukes by 43.9%.⁽³⁾

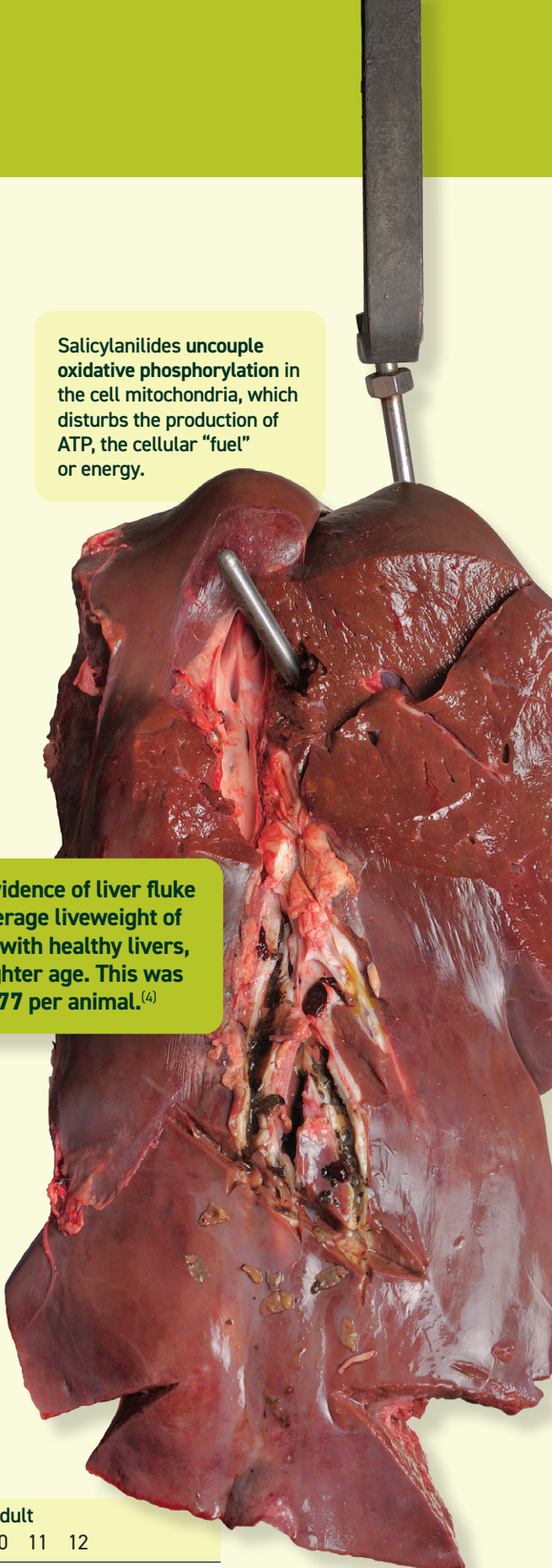
Closantel, by interfering with the energy-demanding processes of gametogenesis and oogenesis, causes a decrease in egg production⁽³⁾ from exposed flukes but does not appear to induce functional defects in the gonads or accessory reproductive organs, so does not affect egg hatchability.

Salicylanilides uncouple oxidative phosphorylation in the cell mitochondria, which disturbs the production of ATP, the cellular "fuel" or energy.



Steers in Ireland with evidence of liver fluke at slaughter had an average liveweight of 36kg less than animals with healthy livers, at a standardised slaughter age. This was an average loss of €77 per animal.⁽⁴⁾

Scottish abattoir data showed that when compared with animals with no liver fluke burden, animals with 1 to 10 parasites take on average 31 days longer to reach slaughter weight, while animals with more than 10 *F. hepatica* flukes in their liver at slaughter take 77 days longer to finish.⁽⁵⁾



Closantel and the liver fluke

| Stage | Early immature | Late immature | Adult |
|----------------------------|--|--|--|
| Fluke age in weeks | 1 2 3 4 5 | 6 7 8 9 | 10 11 12 |
| Fluke activity | Early immature fluke tunnel through liver parenchyma causing permanent scarring to hepatic tissue. | Immature flukes enter the small ducts where they start to ingest blood and develop to sexual maturity. | Adult fluke can reach up to 3cm in size. They live in the large bile ducts and gall bladder feeding on blood prior to egg-laying at 10-11 weeks. |
| Effect of closantel | Stunting / reduction in egg shedding ⁽³⁾ | Kills ≥95% at 7 weeks | Kills ≥95% adult fluke |

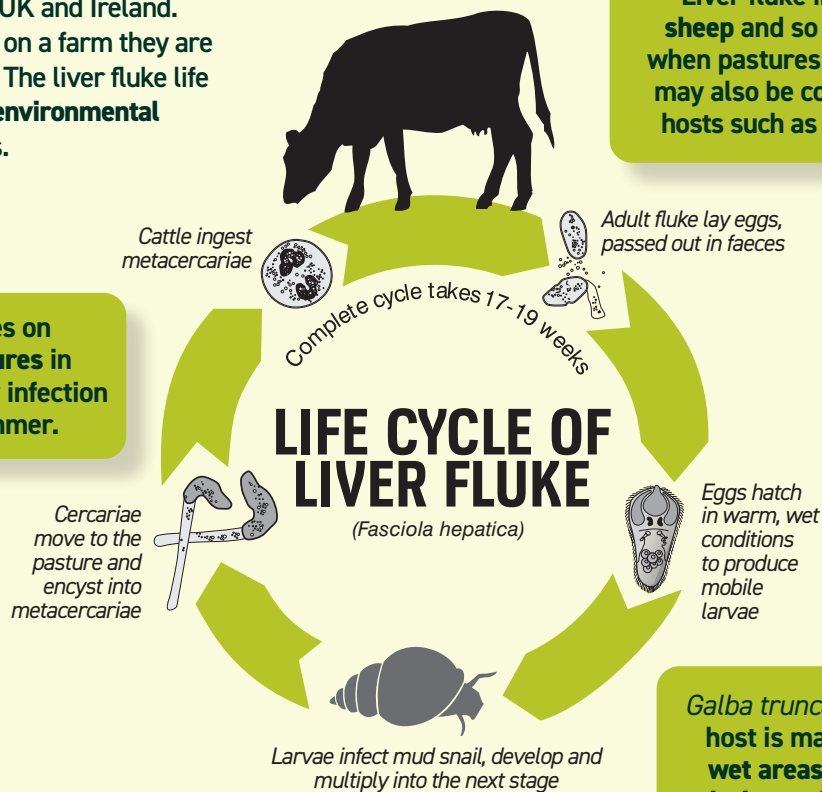


Effective fluke treatment

Liver fluke (*Fasciola hepatica*) are found widely throughout the UK and Ireland. Once fluke are present on a farm they are very hard to eradicate. The liver fluke life cycle is dependent on **environmental** and **climatic** conditions.

Liver fluke infect both cattle and sheep and so the risk may increase when pastures are co-grazed. Pasture may also be contaminated by wildlife hosts such as rabbits, hares or deer.

The fluke risk relies on increased temperatures in spring, leading to likely infection of cattle in late summer.



Galba truncatula, the intermediate host is mainly found in muddy, wet areas of ground with poor drainage; hence the prevalence of fluke is greater in livestock grazing such areas.

Treatment options

Autumn / Winter

Cattle are at the greatest risk of liver fluke infection **from late summer/early autumn on**. Housing marks the end point of exposure to new fluke infection and can be a good time to treat for fluke.

Cattle can be treated **from 7 weeks after housing** to ensure that any fluke within the liver are susceptible at the time of treatment. Where cattle are suffering significant fluke burdens, treatment at or before housing may be appropriate, with a **second, follow-up treatment** later (a period of **at least 10 weeks** between treatments with Solantel Pour-On is required).

Outwintered cattle should be treated during the **late autumn and early winter** and may need a further treatment in **spring**.

Spring / Summer

In high-risk conditions, a treatment **8-10 weeks post turnout** may need to be considered. This will be effective against early infection from the pasture or from fluke that have survived within the cattle during the housing period. If correctly timed, a **mid-summer treatment** with Solantel Pour-On will kill late immature fluke before they start egg-laying, thus reducing pasture contamination.

Dairy Cattle

Solantel is not suitable for use in dairy cattle, but can be used in **youngstock and heifers up to the second half of pregnancy**. Because there are limited flukicides licensed for use in dairy cows and concerns about resistance, this may be an opportunity to introduce an alternative active ingredient as part of a whole herd parasite control plan.

Bought-in Stock

It is recommended that **all bought-in stock** be treated for liver fluke to prevent the introduction of fluke to 'clean' farms and to reduce the risk of resistant fluke being introduced. Treated cattle should be kept separate before being moved to new pasture.

Solantel® 200mg/ml Pour-On Solution for Cattle

Presentation:

Solantel 200mg/ml Pour-On Solution for Cattle is a clear blue/green pour-on solution. Each 1 ml dose contains closantel 200 mg (as closantel sodium dihydrate 217.5 mg).

Uses:

For the treatment of late immature (≥ 7 weeks) and adult *Fasciola hepatica* (fluke) infestations of cattle.

Dosage and administration:

The veterinary medicinal product should be administered topically at a dosage rate of 20 mg closantel per kg bodyweight (1 ml per 10 kg). The formulation should be applied along the midline of the back in a narrow strip between the withers and the tail head.

Assess bodyweight carefully prior to administration. The timing for treatment should be based on epidemiological factors and should be customised for each individual farm.

Single administration only. The product should not be repeatedly applied to cattle within 10 weeks of first administration.

Because of the potential for cross contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. The effect of rain on the pour-on formulation at the time of and after application has not been investigated. For maximum effect animals should be kept indoors or undercover following treatment, when there is rain or an imminent risk of rain.

Withdrawal period:

Cattle (meat and offal): 63 days.

Not authorised for use in cattle producing milk for human consumption, including during the dry period. Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.

All animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period.

Contraindications and warnings:

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

In very rare cases rare (less than 1 animal in 10,000 animals treated, including isolated reports), neurological signs such as blindness, ataxia and recumbency may occur after administration of the product. These cases may also be associated with gastrointestinal signs such as anorexia, diarrhoea and in extreme cases signs may persist and may result in death of the animal. Even though the overall incidence of adverse events is very rare, it has been noted that, when there is an adverse event in a herd, several animals may be affected. Therefore, should neurological signs be observed in one animal, it is recommended to reinforce surveillance, at the herd level, of all treated animals.

Care should be taken to ensure animals are not overdosed by the application volume, accidental spillage or oral ingestion, as overdosage may result in signs of toxicity such as incoordination and blindness. It is recommended that animals are not clipped prior to treatment to reduce the risk of increased drug absorption and hence bioavailability, or oral ingestion through mutual grooming.

Operator warnings:

This product may be toxic after accidental ingestion. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Users should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Avoid skin or eye contact with product. Do not use in cases of known hypersensitivity to polyethylene glycols, povidones, isopropyl alcohol, triethanolamine, ethanol, and/or closantel.

If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention. Wash any exposed skin after use. Protective clothing should be washed after use.

Pharmaceutical precautions:

Shelf life of the veterinary medicinal product as packaged for sale: 16 months.

Shelf life after first opening the immediate packaging: 6 months.

Do not store above 25°C. Store upright in original container in order to protect from light.

Legal category:

UK: POM-VPS ROI: POM

Package quantity:

White 1L, 2.5L and 5L HDPE backpacks for use with a suitable dosing device and white polypropylene screw caps. Not all pack sizes may be marketed.

Disposal:

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Marketing Authorisation numbers:

UK: Vm02000/4442

ROI: VPA22664/150/001

Manufactured and distributed in NI by:

Norbrook Laboratories Limited,
Station Works, Camlough Road, Newry,
Co Down, BT35 6JP.

Distributed in GB by:

Norbrook Laboratories (G.B.) Limited,
1 Saxon Way East, Corby,
Northamptonshire, NN18 8EY.

Distributed in ROI by:

Norbrook Laboratories (Ireland) Limited,
Rossmore Industrial Estate, Monaghan.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

FOR ANIMAL TREATMENT ONLY.

USE MEDICINES RESPONSIBLY.

For further details on these products including the dosage regimens, side effects, precautions, warnings and contraindications please see the summary of product characteristics (SPC) available at:

UK: www.vmd.defra.gov.uk/ProductInformationDatabase/Search

ROI: www.hpra.ie/homepage/veterinary/veterinary-medicines-information/find-a-medicine/

Advice on the use of these products should be sought from the medicine prescriber.

References:

⁽¹⁾ Norbrook Study 001/07.

⁽²⁾ Norbrook Study 024/11.

⁽³⁾ The effect of a parenteral ivermectin/closantel injection on the growth and reproductive development of early-immature *Fasciola hepatica* in cattle. R.E.B, Hanna, L. Cromie, S.M. Taylor, A. Couper. *Veterinary Parasitology* 142 (2006) 78-90.

⁽⁴⁾ The impact of liver fluke infection on steers in Ireland: A meta-analytic approach. Carroll R, Forbes A, Graham D, Locksley L, McV. Messama. *Prev Vet Med* 2020.

⁽⁵⁾ Mazeri S, Rydevik G, Handel I, Bronsvort BMD, Sargison N. Estimation of the impact of *Fasciola hepatica* infection on time taken for UK beef cattle to reach slaughter weight. *Sci Rep.* (2017).

⁽⁶⁾ Vaessen MA, Veling J, Frankena K, Graat EA, Klunder T. Risk factors for *Salmonella* Dublin infection on dairy farms. *Vet Q.* 1998 Jul;20(3):97-9. PubMed PMID: 9684297.

⁽⁷⁾ Fairweather I, Brennan GP, Hanna REB, Robinson MW, Skuce PJ. Drug resistance in liver flukes. *Int J Parasitol Drugs Drug Resist.* 2020;12:39-59. doi:10.1016/j.ijddr.2019.11.003



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⁽⁸⁾ Adapted from Fairweather, I & Boray, J.C. Fasciolides: Efficacy, actions, resistance and its management. *The Veterinary Journal* 158, 81-112. (1999).