National Office of Animal Health

ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

Joint statement from the National Office of Animal Health (NOAH) and the Veterinary Medicines Directorate (VMD) on the use of flukicides in dairy cattle

Flukicides are anthelmintic veterinary medicines that are active against parasites from the trematode class. The main parasite in this class that readers will be familiar with is the frequently occurring parasite liver fluke (*Fasciola hepatica*).

The European Commission, working with the European Medicines Agency, has recently reached a decision that will lead to changes to the Summaries of Product Characteristics (SPCs), Marketing Authorisations (MAs) and labels of many medicines containing flukicides across the European Union.

Vets, Suitably Qualified Persons (SQPs) and farmers are generally required to follow the instructions on the product labels. The prescribing decision rests with the vet or the SQP and when prescribing it is important for them to be aware of withdrawal period requirements specified on the labels. The farmer should follow the advice given by the vet or the SQP.

Below is a summary of the different flukicides (including combination products that also contain anti worming medicines) that are authorised for sale on the UK market and their permitted use in dairy cattle. The table presents the recommended uses in dairy cattle once these products have had their Marketing Authorisations varied and the newly approved labelling has been introduced into the market. It is estimated that this process could take up to 9 months from the end of June 2013. As a consequence, the labels of individual products currently on the market may not be in line with the information presented in the table. It is recommended that the information in the table is followed even if the revised labelling has not been introduced. Whilst using the product as per the current label is allowed, this does carry the risk that residues violations in milk are detected through the residues surveillance scheme run by the VMD as this does examine milk for flukicides.

It should be noted that similar, but not identical, restrictions for use in dairy sheep have also been introduced at the same time.

Vets, Suitably Qualified Persons and farmers are encouraged to discuss any queries they have about the use of a flukicide in dairy animals with the technical department of the Marketing Authorisation Holder (the company who make the product) or with the UK regulatory authority, the Veterinary Medicines Directorate. http://www.vmd.defra.gov.uk/.

As with any product, care is needed to accurately follow the dosing and administration instructions.

It is important to note that the information contained in this table is correct as of the end of June 2013. Further cattle flukicide products may be authorised in the UK and the existing products may be further modified. For the latest information refer to the VMD's product information database: http://www.vmd.defra.gov.uk/ProductInformationDatabase/.

Please also note that this table refers to milk withdrawal periods and use in cows producing milk for human consumption only and does not refer to meat withdrawal periods and use in non-dairy animals.

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Active ingredient - Strength	Route of administration	Authorised for use during LACTATION in DAIRY cattle producing milk for human consumption?	Authorised for use in the DRY PERIOD in pregnant DAIRY cattle producing milk for human consumption?	Authorised for use in PREGNANT MAIDEN DAIRY HEIFERS intended to produce milk for human consumption?	Authorised products (MA Holder)
Closantel 12.5% 125 mg/ml (in combination with ivermectin)	S/C injection	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	Yes, but restrictions apply. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.	Closamectin Solution for Injection for Cattle and Sheep (Norbrook) Closiver Solution for Injection for Cattle (Norbrook) Closivet Solution for Injection for Cattle (Norbrook) Norofas Solution for Injection (Norbrook)
Closantel 20% 200 mg/ml (in combination with ivermectin)	Pour on	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	Yes, but restrictions apply. Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.	Closamectin Pour-On Solution for Cattle (Norbrook) Closiver 5 mg/ml + 200 mg/ml Pour-On Solution for Cattle (Norbrook) Norofas Pour-On Solution for Cattle (Norbrook)
Closantel 5% 50 mg/ml	S/C injection	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	Yes, but restrictions apply. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.	Flukiver Bovis 50 mg/ml Solution for Injection (Eli Lilly)

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Nitroxynil 34% 340 mg/ml	S/C injection	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	Yes, but restrictions apply. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.	Trodax 34% w/v Solution for Injection (Merial)
Triclabendazole 24% 240 mg/ml	Oral	No. The product is not authorised for use in lactating animals producing milk for human consumption	Yes, but restrictions apply. Not intended for use within 48 days of calving. Milk for human consumption may only be taken from 48 hours after calving. Should a cow calve earlier than 48 days after the last treatment, milk for human consumption may only be taken from 50 days after the last treatment.	Yes, but restrictions apply. Not intended for use within 48 days of calving. Milk for human consumption may only be taken from 48 hours after calving. Not intended for use within 48 days of calving. Should a cow calve earlier than 48 days after the last treatment, milk for human consumption may only be taken from 50 days after the last treatment.	Fasinex 240 (Novartis Animal Health)

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Triclabendazole 10% 100 mg/ml	Oral	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	No. Not authorised for use in cattle producing milk for human consumption, including during the dry period.	Yes, but restrictions apply. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption	Endofluke 100 mg/ml Oral Suspension (Cross Vetpharm Group) Fasinex 10% Oral Suspension for Cattle (Novartis Animal Health) Fasinex 100 10% (w/v) Oral Suspension for Cattle and Sheep (Novartis Animal Health) Tribex 10% Oral Suspension for Cattle (Chanelle) Triclacert 10% Oral Suspension for Cattle (Chanelle)
Triclabendazole 20% 200 mg/ml (in combination with moxidectin)	Pour on	No. Do not use in cattle of any age intended to produce milk for human consumption.	No. Do not use in cattle of any age intended to produce milk for human consumption.	No. Do not use in cattle of any age intended to produce milk for human consumption.	Cydectin TriclaMox 5 mg/ml + 200 mg/ml Pour-on Solution for Cattle (Zoetis/Pfizer)
Triclabendazole 12% 120 mg/ml (in combination with levamisole)	Oral	No. Not authorised for use in animals producing milk for human consumption, including during the dry period.	No. Not authorised for use in animals producing milk for human consumption, including during the dry period.	Yes, but restrictions apply. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.	Combinex Cattle Oral Suspension (Novartis Animal Health)

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Albendazole 2.5/10% 25 mg/ml 100 mg/ml	Oral	Yes. Milk withdrawal period of 60 hours applies.	Yes. Milk withdrawal period of 60 hours applies.	Yes. Milk withdrawal period of 60 hours applies.	Albacert 2.5% SC Oral Suspension (Chanelle) Albenil 2.5% w/v SC Oral Suspension (Virbac) Albenil Low Dose 10% w/v Oral Suspension (Virbac) Albensure 10% w/v Oral Suspension (Animax) Albensure 2.5% w/v SC Oral Suspension (Animax) Albex 10% w/v Oral Suspension (Chanelle) Albex 2.5% w/v SC Oral Suspension (Chanelle) Endospec SC 10% w/v Oral Suspension (Cross Vetpharm Group) Endospec SC 2.5% w/v Oral Suspension (Cross Vetpharm Group) Ovispec S & C 10% w/v Oral Suspension (Eli Lilly) Ovispec S & C 2.5% w/v Oral Suspension (Eli Lilly) Tramazole 2.5% w/v SC Oral Suspension (Tulivin Laboratories)

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Oxyclozanideð 30mg/ml (in combination with levamisole)	Oral	No. Do not use in cattle of any age intended to produce milk for human consumption.	No. Do not use in cattle of any age intended to produce milk for human consumption.	No. Do not use in cattle of any age intended to produce milk for human consumption.	Downland Fluke and Worm Oral Suspension (Norbrook) Levafas Diamond Oral Suspension (Norbrook) Levafas Oral Suspension Fluke and Worm Drench (Norbrook)
Oxyclozanide 34mg/ml	Oral	Yes Milk withdrawal period of 72 hours applies.	Yes Milk withdrawal period of 72 hours applies.	Yes Milk withdrawal period of 72 hours applies.	Zanil Fluke Drench 34 mg/ml Oral Suspension (MSD/Intervet)

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Clorsulon 100mg/ml (in combination with ivermectin)	S/C injection	No. Do not use in cattle producing milk for human consumption. .	Yes but restrictions apply. Do not use in non-lactating dairy cows within 60 days of calving. (i.e. do not use if dry period is less than 60 days)	Yes but restrictions apply. Do not use in pregnant heifers within 60 days of calving.	Alverin Plus 10/100 mg/ml Solution for Injection for Cattle (Chanelle) Animec Super Solution for Injection for Cattle (Chanelle) Bimectin Plus, 10/100 mg/ml Solution for Injection for Cattle (Cross Vetpharm Group) Ivermectin and Clorsulon Solution for Injection for Cattle (Virbac) Ivomec Super Injection for Cattle (Merial) Molemec Super Solution for Injection for Cattle (Merial) Supremadex Solution for Injection (Virbac) Virbamec Super Solution for Injection (Virbac)

Key - Red = Do not use at this stage of production; Amber = Use permitted but is restricted (see table for exact restrictions); Green = Use allowed (follow authorised milk withdrawal period during lactation and also when used in non-lactating animals).

Date: 1 July 2013