IRISH MEDICINES BOARD

Notice Information: - Advisory
05 October 2012

Part 1. Product Information

a) Title: Update on Fluke treatments for use in Dairy Cows producing milk for human consumption.

b) Product Name/Type: Update on Fluke treatments for use in Dairy Cows producing milk for human consumption.

Part 2. Target Audience

a) Target Audience: Farming Public & Veterinary Practitioners

Part 3. Background Information

a) Background Information:

Currently two active substances with activity against liver fluke (albendazole and oxyclosanide) are permitted for use in lactating dairy cows. Oxyclosanide and certain products containing albendazole can also be used in pregnant dairy animals during the dry period. Please consult the summary of product characteristics (SPC) or product labelling of individual products containing these substances for information on use in dairy animals.

Regarding the use of flukicides containing other active substances, the overall situation is a dynamic one as explained below.

Following an IMB initiative, maximum residue limits (MRLs) for milk in respect of clorsulon, closantel, nitroxinil, and triclabendazole were established by the European Commission earlier this year. For each of the substances concerned, the net effect of these changes is to remove the existing provision 'Not for use in animals from which milk is produced for human consumption' from the MRL Regulation. The establishment of MRLs for milk in relation to these substances is a welcome development because:

The availability of an MRL is expected to lead to some of the companies concerned commissioning new residue studies in dairy animals producing milk for human consumption to establish appropriate withdrawal times (time between treatment and the production of milk for human consumption), and

The MRL for milk provides a more suitable reference level for residue monitoring purposes.

Within the past number of weeks, the IMB has reviewed new milk residue depletion data for one authorised product containing triclabendazole as active substance (Fasinex 240 Oral Suspension for Cattle, VPA 10825/004/002) following administration of the product in dry-cows. Based on these new data, the IMB approved amendment to the SPC for this specific product to include the following information on use in dairy cattle:

The product is not permitted for use in lactating animals producing milk for human consumption.

Milk for human consumption may only be taken from 48 hours after calving. If calving occurs before 35 days after treatment, milk for huma

human consumption may only be taken after 35 days plus 48 hours after the treatment.

However, as of this time, withdrawal periods for milk have not been set for any of the other similar products containing triclabendazole, nor in respect of the other active substances that have recently gained an MRL for milk. Until product specific withdrawal periods are set for either dry cows or milking cows (being dependent on the available of new residue data), the existing prohibition on use of the products concerned in dairy cows remains in place. That is, such products are: ”Not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.”

Under a different EU procedure, the IMB is awaiting the outcome of a European Commission Decision to harmonise the labelling warnings / withdrawal period recommendations in dry cows and pregnant heifers between products containing flukicidal substances, marketed in different EU Member States. This may facilitate the use of some other flukicidal products in pregnant dairy animals, subject to certain restrictions that will be specific to the individual substances and product types. This development, if/when confirmed by the EU Commission, is expected to result in a (marginal) change to the existing warnings (the current prohibition on use in animals intended for milk production is expected to be nuanced more precisely e.g. prohibition on use during pregnancy or in last trimester of pregnancy depending on the drug concerned). Again, until such time as a decision is reached, the current prohibition remains in place in respect of the products concerned.

Pending further developments, the IMB will provide a further update on the situation in due course.

Part 4. Enquiries

a) All enquiries should be made to:

Queries in relation to the above item can be sent to the Veterinary Department at the following email address vetinfo@imb.ie