

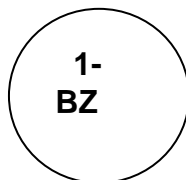
Guide to Display of Chemical Group Symbols on Product Literature of Sheep Anthelmintics

1 CHEMICAL GROUP SYMBOLS OF SHEEP ANTHELMINTICS

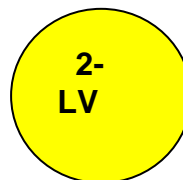
The HPRA accepts applications to amend the product literature of sheep anthelmintics to display the chemical group symbols. The initiative is a voluntary one and has been introduced in order to enable easy identification of the chemical group through the use of approved symbols. It is anticipated that this will minimise overuse or continued use in instances where resistance has been confirmed. The scheme is already in place in the UK and the symbols to be used in Ireland are identical to those used in the UK.

The symbols consist of a circular design with a designated colour and the anthelmintic group code. The symbols should be located in a prominent position on the outer carton, immediate label and package leaflet. A minimum diameter of 10 mm is suggested for the symbol on the outer packaging (this size can be scaled up for larger packs). No symbol is required for narrow spectrum anthelmintics e.g. closantel. For example closantel-only drench will not display any symbol; closantel/mebendazole combination drench will display the 1-BZ symbol only.

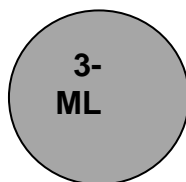
The chemical group symbols to be used are:



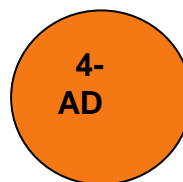
Benzimidazoles



Levamisole



Macrocyclic Lactones



Amino-acetonitrile Derivatives



Spiroindoles

Amended product literature should be submitted through a type IB C.II.6 variation. Only the specific amendment may be made and no other changes will be considered or approved as part of the C.II.6 variation. No fee will apply and there is no time limit for submission.

The HPRA also accepts addition of the symbols during the assessment of other variations/renewals affecting the product literature.

This is a voluntary initiative designed to reduce nematode resistance in sheep. We encourage all applicants to partake in this initiative. Applicants that have already amended joint labels in accordance with this initiative should consider moving the symbol from the UK-only box to the general text.

Further information on the application procedure to introduce the symbols may be obtained by contacting the HPRA (vetcoordination@hpra.ie).

HPRA
January 2015