Norbrook®

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Updated Summary of Product Characteristics (SPC) and Labelling for Solantel 50 mg/ml Oral Suspension for Sheep

Dear Veterinary Surgeon and Suitably Qualified Person (SQP),

Norbrook Laboratories (GB) LTD in agreement with the Veterinary Medicines Directorate (VMD) would like to inform you of the following change to the aforementioned product.

Subsequent to a variation to extend the withdrawal period to slaughter for sheep from 42 days to 56 days, our standard SPC and Norbrook GB labelling for **Solantel 50 mg/ml Oral Suspension for Sheep** (Vm 02000/4402) will be changing.

Please find below details of the changes - Norbrook would ask that users respect these new withdrawal periods with **immediate effect** pending the availability of new stock with updated labelling reflecting the revised withdrawal periods.

CURRENT TEXT ON THE SUMMARY OF PRODUCT CHARACTERISTICS (SPC)	NEW TEXT ON THE SUMMARY OF PRODUCT CHARACTERISTICS (SPC)
4.11 Withdrawal period(s) Meat and offal: 42 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.	**4.11 Withdrawal period(s)** Meat and offal: 56 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

CURRENT TEXT – PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)	NEW TEXT – PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)
8. WITHDRAWAL PERIOD Withdrawal period: Meat and offal: 42 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in	**8. WITHDRAWAL PERIOD** Withdrawal period: Meat and offal: 56 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in

ewes intended to produce milk for human consumption.	ewes intended to produce milk for human consumption.

CURRENT TEXT – PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL, Backpack)	NEW TEXT – PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL, Backpack)
8. WITHDRAWAL PERIOD Withdrawal period: Meat and offal: 42 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.	**8. WITHDRAWAL PERIOD** Withdrawal period: Meat and offal: 56 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

CURRENT TEXT – PACKAGE LEAFLET	NEW TEXT – PACKAGE LEAFLET
10. WITHDRAWAL PERIOD(S) Meat and offal: 42 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.	**10. WITHDRAWAL PERIOD(S)** Meat and offal: 56 days Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

If you would like any further information or guidance about the change to this SPC or product information sheet, please contact us (gbenquiries@norbrook.co.uk).

Any adverse event following the use of any veterinary medicine should be reported either to the manufacturer of the veterinary medicine or directly to the VMD by emailing adverse.events@vmd.gov.uk.

Yours sincerely,

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Ned Flaxman
General Manager
Norbrook Laboratories (GB) Ltd