

## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

### CARTON

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closamectin 5 mg/ml + 200 mg/ml Pour-On Solution for Cattle

#### 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ivermectin	5 mg
Closantel	200 mg
(as closantel sodium dihydrate)	217.5 mg

#### 3. PACKAGE SIZE

250 ml

500 ml

1 l

2.5 l

5 l

#### 4. TARGET SPECIES

Cattle.

#### 5. INDICATIONS

#### 6. ROUTES OF ADMINISTRATION

Pour-on use.

For external use only.

#### 7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 58 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.

Due to the significant likelihood of 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. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

#### 8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

<b>9. SPECIAL STORAGE CONDITIONS</b>
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Do not store above 25 °C. Protect from light.

Flammable – keep away from heat, sparks, open flame or other sources of ignition.

If stored at temperatures below 0°C, the veterinary medicinal product may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

Accidental spillage or ingestion could be detrimental or even fatal therefore care should be taken when handling and storing this product.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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Norbrook Laboratories (Ireland) Limited

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

### **LABEL**

#### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Closamectin 5 mg/ml + 200 mg/ml Pour-On Solution for Cattle

#### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Ivermectin	5 mg
Closantel	200 mg
(as closantel sodium dihydrate 217.5 mg)	

#### **3. TARGET SPECIES**

Cattle.

#### **4. ROUTES OF ADMINISTRATION**

**Pour-on use.**

For external use only.

#### **5. WITHDRAWAL PERIODS**

Withdrawal period:

Meat and offal: 58 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.

Due to the significant likelihood of 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. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

#### **6. EXPIRY DATE**

Exp. {MM/YYYY}

Once opened use immediately

#### **7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C. Protect from light.

If stored at temperatures below 0°C, the veterinary medicinal product may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Flammable – keep away from heat, sparks, open flame or other sources of ignition.  
Store upright in original container.

<b>8. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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Norbrook Laboratories (Ireland) Limited

<b>9. BATCH NUMBER</b>
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Lot {number}