

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard box with vial(s) of 10 ml, 20 ml, 50 ml and 100 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synchromate 0.25 mg/ml, Solution for injection for cattle, pigs and horses

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Cloprostenol 0.25 mg

(Corresponds to Cloprostenol sodium 0.263 mg)

3. PACKAGE SIZE

1 X 10 ml

5 X 10 ml

12 X 10 ml

1 X 20 ml

12 X 20 ml

1 X 50 ml

1 X 100 ml

4. TARGET SPECIES

Cattle, pigs and horses

5. INDICATION(S)

6. ROUTE OF ADMINISTRATION

Cattle, pigs and horses: intramuscular use.

7. WITHDRAWAL PERIOD

Withdrawal period:

Cattle (cows):

Meat and offal: 2 days

Milk: Zero days

Pig (sows):

Meat and offal: 2 days

Horses (mares):

Meat and offal: 28 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Use by

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Alivira Animal Health Limited

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synchromate 0.25 mg/ml, Solution for injection for cattle, pigs and horses

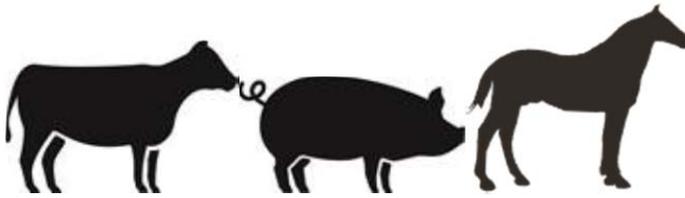
2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Cloprostenol 0.25 mg

(Corresponds to Cloprostenol sodium 0.263 mg)

3. TARGET SPECIES



Cattle, pigs and horses

4. ROUTES OF ADMINISTRATION

Cattle, pigs and horses: intramuscular use

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle (cows):

Meat and offal: 2 days

Milk: Zero days

Pig (sows):

Meat and offal: 2 days

Horses (mares):

Meat and offal: 28 days.

6. EXPIRY DATE

EXP. {mm/yyyy}

Once broached use by

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alivira Animal Health Limited

9. BATCH NUMBER

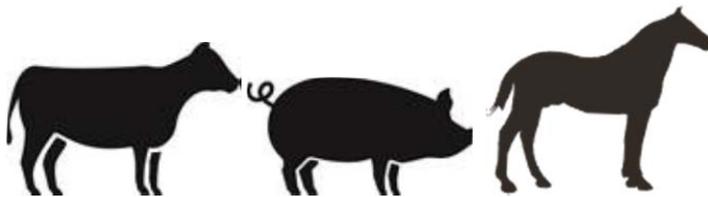
Lot{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (10 ml, 20ml & 50ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Synchromate



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Cloprostenol 0.25 mg

(Corresponds to Cloprostenol sodium 0.263 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Use by

