

[Version 9,03/2022]

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 vial of 20 ml
Box with 5 vials of 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

In Belgium, Bulgaria, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Portugal, Romania, Slovakia, Spain and The Netherlands;

LUTEOSYL 0.075 mg/ml solution for injection.

In United Kingdom: Prellim 0.075 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

d-Cloprostenol (as d-Cloprostenol sodium) 0.075 mg

3. PACKAGE SIZE

20 ml
5 x 20 ml

4. TARGET SPECIES

Cattle (cows) and pigs (sows).

5. INDICATION(S)**6. ROUTE(S) OF ADMINISTRATION**

Intramuscular use.

7. WITHDRAWAL PERIOD

Withdrawal period:

Cows: Meat and offal: 1 day.
Milk: Zero hours.

Sows: Meat and offal: 1 day.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, used within 28 days.

Once opened used 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

Laboratorios Syva S.A.

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS
VIAL OF 20 ML**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

In Belgium, Bulgaria, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Portugal, Romania, Slovakia, Spain and The Netherlands;

LUTEOSYL 0.075 mg/ml solution for injection.

In United Kingdom: Prellim 0.075 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Each ml contains:

d-Cloprostenol (as d-Cloprostenol sodium) 0.075 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, used within 28 days.

Once opened used by...