

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE PACKAGE

{box with 1 vial of 6, 20, 50, 100 ml and box with 10 vials of 6 ml. Vials of 50 and 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RELOSYL 50 micrograms /ml solution for injection for cattle.

Gonadorelin (as acetate).

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml contains:

Active substance:

Gonadorelin (as gonadorelin acetate).....50 µg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

6 ml/

20 ml, 50 ml, 100 ml, 10 x 6 ml

5. TARGET SPECIES

Cattle: Cows and heifers.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: zero days.

Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached, use by:

Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Keep the vial in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA, S.A.
Calle Marqués de la Ensenada, 16
28004 Madrid
Spain

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Vials 6 ml/ 20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RELOSYL 50 micrograms/ml solution for injection for cattle.

Gonadorelin (as acetate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Gonadorelin (as gonadorelin acetate).....50 µg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6 ml/20 ml

4. ROUTE OF ADMINISTRATION

Intramuscular use

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: zero days

Milk: zero hours

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

Once opened, use by:

Shelf life after first opening the immediate packaging: 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.