

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**{BOX 100 ml}****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CALIDEX - G 200 mg/ml SOLUTION FOR INJECTION FOR PIGS

Iron (as gleptoferron)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Iron (as gleptoferron)200.0 mg

Excipients:

Phenol 5.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pig (Piglet)

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use by...

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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

Disposal: read 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.

To be administered by a veterinary surgeon or under their direct responsibility

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 CALIER, S.A.
C/ Barcelonés, 26 (El Ramassar)
LES FRANQUESES DEL VALLES, (Barcelona)

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

Batch number:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE UNITS

{LABEL 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CALIDEX - G 200 mg/ml SOLUTION FOR INJECTION FOR PIGS

Iron (as gleptoferron)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substances:

Iron (as gleptoferron) 200.0 mg

Excipients:

Phenol 5.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pig (Piglet)

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use by...

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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

Disposal: read 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.

To be administered by a veterinary surgeon or under their direct responsibility

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
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Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

C/ Barcelonés, 26 (El Ramassar)

LES FRANQUESES DEL VALLES, (Barcelona)

16. MARKETING AUTHORISATION NUMBER(S)
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17. MANUFACTURER'S BATCH NUMBER
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Batch number: