B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
CALIDEX - G 200 mg/ml SOLUTION FOR INJECTION FOR PIGS

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
LABORATORIOS CALIER, S.A.
C/ Barcelonés, 26 (El Ramassar)
LES FRANQUESES DEL VALLES, (Barcelona)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CALIDEX - G 200 mg/ml SOLUTION FOR INJECTION FOR PIGS
Iron (as gleptoferron)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substances:
Iron (as gleptoferron).....200.0 mg

Excipients:
Phenol..... 5.0 mg

4. INDICATION(S)

For prophylaxis and treatment of iron deficiency anaemia in piglets.

5. CONTRAINDICATIONS

Do not use in piglets suspected to suffer from deficiency of vitamin E and/or selenium. Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in clinically diseased animals, especially not in case of diarrhoea.

6. ADVERSE REACTIONS

Discolouration of the tissue and/or slight, soft swelling may be observed at the site of injection uncommonly. This should disappear within a few days. Also hypersensitivity reactions can occur uncommonly.
Deaths in piglets following the administration of parenteral iron dextran preparations have occurred in rare cases. These deaths have been associated with genetic factors or deficiency of vitamin E and/or selenium.
Deaths in piglets, which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system, have been reported very rarely.

"*The frequency of adverse reactions is defined using the following convention:*
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)."

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon."

7. TARGET SPECIES

Pig (piglet)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For strictly intramuscular injection.

Piglets:
200 mg Fe^{3+} per animal which is equivalent to
1 ml of the product per animal.
Inject once between the 1st and the 3rd day of life.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Meat and offal: Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelflife after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Normal aseptic injection techniques should be practised. Avoid the introduction of contamination during use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to the active substance (gleptoferron) or with hemochromatosis should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection as well as mucous membrane contact, especially people with known hypersensitivity to iron dextran.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Interaction with other medicinal products and other forms of interaction:
The absorption of concomitantly administered oral iron may be reduced.

Overdose (symptoms, emergency procedures, antidotes):
Transferrin-iron saturation levels leading to increased susceptibility for (systemic) bacterial disease, pain, inflammation reactions as well as abscess formation at the injection site may occur.
Persistent discolouration of muscle tissue at the injection site may occur.
Iatrogenic poisoning with following symptoms: pale mucous membranes, hemorrhagic gastroenteritis, vomiting, tachycardia, hypotension, dyspnoea, edema of the limbs, lameness, shock, death, liver damage. Supportive measures such as chelating agents can be used.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Use veterinary. Veterinary medicinal product subject to prescription.
To be administered by a veterinary surgeon or under their direct responsibility.