SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
CALIDEX – G 200 mg/ml SOLUTION FOR INJECTION FOR PIGS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml contains:

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

Excipients:
Phenol ..... 5.0 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for injection.
A dark brown, slightly viscous, sterile, colloidal, aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species
Pig (piglet)

4.2 Indications for use, specifying the target species
For prophylaxis and treatment of iron deficiency anaemia in piglets.

4.3 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.

4.4 Special warnings for each target species
None

4.5 Special precautions for use
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 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.

4.6 Adverse reactions (frequency and seriousness)

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)."

4.7 Use during pregnancy or lactation

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

The absorption of concomitantly administered oral iron may be reduced.
See also section 6.2.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

Meat and offal: Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Iron, parenteral preparations.
ATCvet Code: QB03AC

5.1 Pharmacodynamic properties

Iron is an essential micronutrient. It takes a major role in the oxygen transport of haemoglobin and myoglobin, as well as it has a key role in enzymes, such as cytochromes, catalases, and peroxidases.
Iron has a high recovery rate from metabolism and food ingested. Thus, deficiency occurs only very rarely in adult animals.

5.2 Pharmacokinetic particulars

After intramuscular injection, the iron complex is absorbed into the lymphatic tissue within 3 days. Here, the complex is split to release Fe^{3+} which is stored as ferritin in the main storage organs (e.g. liver, spleen and the reticuloendothelial system). In the blood, free Fe^{3+} binds to transferrin (transport form) and is mainly used for the synthesis of haemoglobin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol (preservative)
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf-life after first opening of the container: 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Amber glass vials, quality European Pharmacopoeia II, of 100 ml of capacity, provided with bromobutyl rubber stopper and aluminium caps flip off seal

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

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