IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10995/025/001
Case No: 7002387

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ceva Animal Health Limited

90 The Broadway, **Chesham**, **Bucks HP15 1EG**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Roscodex 150 Solution for Injection

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Roscodex – 150 Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:		
Iron Dextran Complex equivalent to elemental iron	150	mg
Excipients		
*Liquid Phenol	5.6	mg
Water for Injection to	1.0	ml

*Equivalent to 5mg of solid phenol

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Piglets.

4.2 Indications for use, specifying the target species

Prophylaxis and treatment of iron deficiency anaemia.

4.3 Contraindications

Do not use in piglets over 4 weeks of age because of an increased risk of ham staining at the injection site.

4.4 Special warnings for each target species

If used in piglets with vitamin E and/or selenium deficiency, iron toxicosis can occur.

4.5 Special precautions for use

Special precaution for use

Ensure strict aseptic procedures at injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Usual safety precautions when administering injections to animals.

4.6 Adverse reactions (frequency and seriousness)

Occasional deaths have occurred in piglets following the administration of parenteral iron dextran preparations. These have been associated with maternal dietary deficiency of vitamin E and/or selenium.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Avoid simultaneous (in the same syringe) administration with tetracycline and sulphadiazine solutions.

4.9 Amounts to be administered and administration route

Administration is by intramuscular or subcutaneous (inguinal fold) injection.

Piglets: 1 ml [150 mg iron] administered between the 2nd and 4th day after birth.

It is advisable to stretch the skin over the injection site with the thumb prior to inserting the needle, to prevent leakage on withdrawal.

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

Overdosing with iron dextran at 750 mg/kg bodyweight administered parenterally to piglets can cause the following symptoms: abnormal movements, drowsiness, dyspnoea, cardiovascular collapse, brown discolouration of the skin, death.

4.11 Withdrawal Period(s)

Piglets intended for human consumption should not be slaughtered until 30 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Iron is vital for animals. It forms an integral part of myoglobin and haemoglobin, which are used in the transportation and utilisation of oxygen in the body. Iron is also a component of vital enzymes in the body. After injection the iron dextran is absorbed mainly through the lymph and is transported by the blood to the reticulo-endothelial system in the body. The dextran is eliminated in the urine, and some is metabolised into glucose, while the iron is used for the synthesis of haemoglobin.

Roscodex™ 150 is a solution of iron dextran complex of low viscosity and low toxicity. It is non-irritant and rapidly absorbed from the injection site without staining.

The high concentration of Fe (III) in Roscodex™ 150 reduces the injection volume.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Phenol
Water for Injection

6.2 Incompatibilities

Do not mix (in the same syringe) with other preparations.

6.3 Shelf-life

The shelf-life expiry date for this product shall not exceed two years from the date of its manufacture.

Any content of product remaining later than 28 days of first broaching the seal shall be discarded.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Plastic vial 100 ml (polyethylene HDPE Ph. Eur)
Tropical stopper, butyl-rubber PH 4002/45.
Metal cap without rubber (ring shaped).

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Ceva Animal Health
90 The Broadway Chesham
Bucks HP5 1EG
Great Britain

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/25/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004