IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10900/010/001**
Case No: 7007757

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Ark Animal Care Ltd

Newbridge, **Co. Kildare**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Anaemex 200mg/ml Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **27/04/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Anaemex 200 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Elemental Iron as Iron Dextran Complex 200 mg

Excipients
Phenol 5 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A reddish brown solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Young pigs

4.2 Indications for use, specifying the target species

For treatment and prevention of iron deficiency anaemia in piglets.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.
Do not use for intravenous administration.
Not for use in pigs over 4 weeks of age.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

None.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Rarely, anaphylactic reactions may occur following use of the product.
Sudden deaths have occurred sporadically in piglets following the administration of iron. These deaths may be associated with Vitamin E/Selenium deficiency.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

For deep intramuscular injection in the neck.
1 ml by deep intramuscular injection at 3-4 days of age.
It is advisable to stretch the skin over the injection site prior to inserting needle to prevent leakage on withdrawal.

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

None

4.11 Withdrawal Period(s)

Meat and offal: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Blood and blood forming organs, antianemic preparations, iron trivalent, parenteral preparations, iron dextran.

ATC vet code: QB03AC90

For treatment of clinical anaemia.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Hydrochloric acid
Sodium hydroxide
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 medicianl product as packaged for sale in glass vials: 5 years.
Shelf life of the veterinary medicianl product as packaged for sale in HDPE vials: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

100 ml clear Type II glass vials, fitted with bromobutyl stoppers and gold aluminium seal.

100 ml HDPE vials, fitted with bromobutyl stoppers and aluminium seal.

Not all pack sizes may be marketed.

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

None.

7 MARKETING AUTHORISATION HOLDER

Ark Animal Care Ltd.,
Newbridge,
Co. Kildare.
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10900/010/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

27th April 2010