

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10545/029/001**

Case No: 7004500

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:

Janssen Cilag Ltd.

50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, United Kingdom

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:

Jancare 15 %w/v Oral Suspension

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 **09/07/2008** until **18/10/2009**.

Signed on behalf of the Irish Medicines Board

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

Jancare Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Albendazole 15 % w/v

Selenium (as sodium selenate) 0.15 % w/v

Excipients

Potassium Sorbate 0.18 % w/v

Formaldehyde 0.20 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Mature cattle and calves.

4.2 Indications for use, specifying the target species

Effective against benzimidazole sensitive mature and immature roundworms, including Type II ostertagia, lungworms, tapeworms and adult liver fluke in cattle.

Also kills worm and fluke eggs.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

Do not use in cattle producing milk for human consumption.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Assess bodyweight as accurately as possible before calculating dosage. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Direct contact with the skin should be kept to a minimum.

Wear suitable protective clothing including impermeable rubber gloves.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not use in cattle producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use at the same time as any other selenium containing product without consulting a veterinarian.

4.9 Amounts to be administered and administration route

Shake well before use.

Using standard drenching equipment administer orally.

Cattle: Worm infestations - 7.5mg albendazole per kg bodyweight (0.75ml per 15kg bodyweight). This dose also delivers 0.073 mg per kg Selenium.

Worm and fluke infestations - 10mg albendazole per kg bodyweight (1ml per 15kg bodyweight). This dose also delivers 0.097mg per kg Selenium.

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

The product is very well tolerated at the recommended dose rates. In the case of accidental overdosage, depression and anorexia may occur.

4.11 Withdrawal Period(s)

Meat. 14 days. Animals intended for human consumption may only be slaughtered from 14 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Albendazole acts on parasites by interfering with their energy generating metabolism. It inhibits fumarate reductase, which in turn prevents the generation of mitochondrial energy in the form of adenosine triphosphate (ATP). There is other evidence that the mode of action is the prevention of microtubule polymerisation. Differential binding affinities between nematode and mammalian tubulin may explain the selective toxicity of benzimidazoles.

In calves, peak plasma levels equivalent to 5.5 micrograms of albendazole and /or metabolites are achieved 15 hours after the administration of an oral dose of 20mg radio-labelled albendazole per kg bodyweight. Twenty-eight percent of the administered dose is excreted in urine during the first 24 hours, and 47% is excreted over a 9-day period.

Albendazole is metabolised primarily to its sulphoxide and sulphone, which are excreted mostly through the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Citric Acid
Colloidal Anhydrous Silica
Formaldehyde Solution
Monopropylene glycol
Polyethylene glycol 6000
Polyoxyl 40 stearate
Potassium Sorbate
Xanthan Gum
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

The expiry date shall not be more than 24 months from the date of manufacture.

6.4 Special precautions for storage

Do not store above 25°C
Protect from light and frost
Store in tightly closed original container
Shake container well before use.

6.5 Nature and composition of immediate packaging

Container: White food grade, high density polyethylene pack.
Closure: HDPE screw cap.
Pack Size: 1, 2.5 and 5 Litres

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

Janssen - Cilag Ltd.
50 - 100 Holmers Farm way
High Wycombe,
Buckinghamshire,
HP12 4EG,
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10545/29/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th October 2004

10 DATE OF REVISION OF THE TEXT

9th July 2008