IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10545/033/001**
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:

Janamax Pour-On for cattle

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 **12/06/2011**.

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

Janamax Pour-On for Cattle 1%w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:	
Abamectin	1% w/v
Excipients:	
Benzyl Alcohol	

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Pour-on Solution
Clear straw coloured oily liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Beef and non-lactating dairy cattle)

4.2 Indications for use, specifying the target species

A broad spectrum endectocide of the avermectin family, effective against internal and external parasites sensitive to this family.

For the treatment and control of the following mature and immature roundworms in cattle:

Gastro-intestinal nematodes:

- Haemonchus spp.
- Ostertagia spp.
- Cooperia spp.
- Trichostrongylus spp.
- Oesophagostomum spp.
- Nematodirus spp.
- Trichuris spp. (adults only)
- Dictyocaulus spp.

Also for the treatment and control of sucking and biting lice (*Linognathus vituli* and *Damalinia bovis).*

4.3 Contraindications

Do not concurrently treat animals with drugs, which can increase GABA activity such as barbital.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not use in other species.
Assess bodyweight as accurately as possible before calculating dosage.
Intensive use or misuse of anthelmintics may give rise to drug resistance. To reduce this risk, dosing programs should be discussed with your veterinary surgeon.

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

Avoid contact with the skin.
Do not eat, drink or smoke whilst handling the product.
Operators should wear rubber gloves and boots with a waterproof coat when applying the product
Protective clothing should be washed after use
Wash hands after use.
Accidental spillage on the skin should be washed off immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with clean water
In case of accidental injection, induce vomiting and seek medical care.
Read label before use

4.6 Adverse reactions (frequency and seriousness)

None.

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

None known.

4.9 Amounts to be administered and administration route

Janamax Pour-on for cattle is ready to use through standard pour-on equipment.

Shake well before use.

Cattle: 1ml/20kg bodyweight (based on the recommended dose of 500 micrograms of abamectin per kg bodyweight) poured on the mid-back of the animal.

Rain Resistance: Clinical trials have shown that the efficacy of Janamax Pour-on is not affected by simulated rainfall 1 hour after treatment based on faecal egg counts 3 weeks after treatment. It is advised not to treat cattle when the hide or hair is wet.

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

Clinical trials showed that a dose of 1000 µg/kg single or repeated after 21 days caused no adverse drug reactions; however several fold overdose of the injectable formulation of abamectin can cause toxicity; animals will become recumbent within 24 hours and may not recover; there is no antidote.

4.11 Withdrawal Period(s)

Cattle must not be treated within 35 days of slaughter for human consumption.
Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

QP54A Macrocyclic lactone

Abamectin or Avermectin B_1 is the natural fermentation product from *Streptomyces avermitilis* containing not less than 90% of the B_{1a} component and not more than 10% of the B_{1b} component.

5.1 Pharmacodynamic properties

The action of avermectins is on nematode and arthropod parasites by paralysing them through potentiating the presynaptic release of gamma amino butyric acid (GABA).

5.2 Pharmacokinetic properties

The pharmacokinetic profile of avermectins can be influenced by the formulation used. Janamax Pour-on is formulated in a carrier vegetable oil base. Vegetable oils are preferred to effectively cause permeation through the skin. This was reflected by the persistent (35 days) blood levels of abamectin.

Avermectins are widely dispersed in all tissues with the liver and fat levels being the highest. Excretion is mainly intra intestinal, through bile, and the drug is eliminated via the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Soya Bean Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1L and 2.5L black jerry cans consisting of fluorinated HDPE

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

Any unused product or waste material should be disposed of in accordance with national requirements.

Abamectin is extremely dangerous to fish and other aquatic life. Any unused medicine or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10545/33/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13th June 2006

10 DATE OF REVISION OF THE TEXT

9th July 2008