

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10879/021/001**

Case No: 7007540

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:

Chanelle Animal Health Ltd.

7 Rodney Street, Liverpool L1 9HZ, England

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:

Anisec 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 **12/04/2010** until **26/07/2010**.

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

Anisec Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:

Ivermectin 1.0% w/v (10 mg/ml)

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Pigs

4.2 Indications for use, specifying the target species

Anisec Injection is indicated for the treatment of the following parasites of cattle and pigs:

Cattle:

Gastro-intestinal roundworms (adult and fourth stage larvae):

Ostertagia spp (including inhibited *O. ostertagi*),
Haemonchus placei,
Trichostrongylus axei,
Trichostrongylus colubriformis,
Cooperia spp,
Oesophagostomum radiatum,
Strongyloides papillosus (adult)

Nematodirus helvetianus (adult),
N. spathiger (adult)
Toxocara vitulorum,
Trichuris spp. (adult).

Lungworms (adult and fourth stage larvae) :

Dictyocaulus viviparus.

Eye worms (adult):

Thelazia spp.

Warbles (parasitic stages):

Hypoderma bovis and *H. lineatum*.

Mange mites :

Psoroptes communis var. *bovis*,
Sarcoptes scabiei var. *bovis*.

Sucking lice :

Linognathus vituli,
Haematopinus eurysternus

May also be used as an aid in the reduction of infestation of the mange mite *Chorioptes bovis* but complete elimination may not occur.

Pigs:

Gastrointestinal worms (adult and fourth stage larvae):

Ascaris suum,
Hyostromylus rubidus,
Oesophagostomum spp,
Strongyloides ransomi (adult stage)

Lungworms:

Metastrongylus spp. (adult)

Lice:

Haematopinus suis

Mange mites:

Sarcoptes scabiei var. *suis*

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

Do not use in lactating dairy cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers within 60 days of calving.

Do not administer by the intravenous or intramuscular route.

4.4 Special warnings for each target species

Details provided above apply. See also points 4.3, 4.5 and 4.7.

4.5 Special precautions for use

Special precautions for use in animals

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal results are reported in dogs especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid under-dosing, animals should be grouped according to their bodyweight and dosed according to the dose of the heaviest animal in the group.

In Cattle:

The volume administered per injection site should not exceed 10ml.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

Do not combine treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

In Pigs:

The volume administered per injection site should not exceed 5ml.

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

Take care to avoid self administration; the product may cause local irritation and or/pain at the site of injection.

Do not smoke or eat while handling the product.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Pigs

Mild and transient pain reactions may be seen in some pigs following subcutaneous injection.

All these reactions disappeared without treatment.

4.7 Use during pregnancy, lactation or lay

The product can be administered during pregnancy in cows. Do not use in lactating dairy cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers within 60 days of calving.

In pigs, the product can be used in breeding sows and boars. Do not administer the product in pigs during the first 40 days of pregnancy. The fertility of males is not affected by administration of the product.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle, and 33 kg of bodyweight of pigs. The injection may be given with any standard automatic on single-dose or hypodermic syringe. Use of 17 gauge x 1/2 inch needle is suggested.

Cattle

Anisec Injection should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle. This is equivalent to 1 ml per 50 kg bodyweight.

Pigs

In pigs, the recommended dosage level is 300 mcg ivermectin per kg bodyweight. This is equivalent to 1 ml per 33 kg bodyweight. The recommended route of administration is by subcutaneous injection into the neck.

Young Pigs

In young pigs, especially those below 16 kg for which less than 0.5 ml Anisec Injection is indicated, dosing accurately is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.

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

Cattle

Single dose of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

Pigs

A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

Cattle and Pigs

No systemic or local signs of toxic effects were reported at 3 times the recommended dose in both species, cattle and pigs.

4.11 Withdrawal Period(s)

Cattle

Meat and offal: 49 days

Do not use in lactating dairy cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers within 60 days of calving.

Pigs

Meat and offal: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QP54AA01.

Pharmacotherapeutic Group: Endectocides

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides. Compounds of this class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels. The macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic properties

Maximum plasma concentration

Cattle

At a dose level of 0.2 mg ivermectin per kg a C_{max} of 30 ng/ml is reached at a T_{max} of 131 hours with an elimination half-life of 5.9 days. It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Pigs

At a dose level of 0.3 mg ivermectin per kg bodyweight, a mean C_{max} of 6.94 ng/ml was reached at a mean T_{max} of 86.75 hours, and the mean elimination half life was 133.56 hours.

Excretion: length of time and route

Cattle

Only about 1 - 2% is excreted in the urine, the remainder is excreted in the faeces approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products.

Pigs

Biliary excretion is also the major route of ivermectin excretion in pigs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

None known.

6.3 Shelf-life

Unopened vial: 36 months

Following withdrawal of the first dose use the product within 28 days.

6.4 Special precautions for storage

None.

6.5 Nature and composition of immediate packaging

Multidose polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and aluminium overseals

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

Extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with product or used container. Unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.,
7 Rodney Street,
Liverpool L19 4HZ,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10879/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27th July 2005

10 DATE OF REVISION OF THE TEXT