IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/125/001**
Case No: 7005918

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:

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Dublin 24**, **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:

Taktic 12.5% w/v Concentrate for dip emulsion

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 previously revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

_____

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Taktic 12.5% w/v Concentrate for dip emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Amitraz 125 g/litre

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for dip emulsion

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs, cattle and sheep.

4.2 Indications for use, specifying the target species

Pigs: For the treatment and control of sarcoptic mange and lice.
Cattle: For the treatment and control of ticks, mange mites and lice.
Sheep: For the treatment and control of ticks and mange mites and for the treatment of lice and keds.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

Do not dip tired or thirsty animals.

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

When handling concentrate or when spraying: Wear water proof overalls, rubber gloves (neoprene or nitrile of minimum thickness 0.5 mm), rubber boots and face shield when opening containers, diluting or spraying animals with diluted product or when washing out empty containers.

When handling dip concentrate or working with diluted dip and freshly dipped sheep: Wear rubber gloves (heavy-duty gauntlet style nitrile at least 300 mm in length and 0.5 mm thick), rubber boots, waterproof trousers or leggings and coat or bib-apron and a face shield when handling the concentrate. Dipping should be carried out in a well ventilated area, preferably outdoors.

When using, do not eat, drink or smoke. Do not breathe spray mist. Avoid all contact with mouth, skin and eyes.

Wash concentrate or splashes of diluted spray from skin or eyes immediately. Wash all protective clothing thoroughly after use, especially the inside's of gloves. Wash hands and exposed skin before eating, drinking or smoking after work.
GUIDE TO DOCTOR: Amitraz is NOT an organophosphorus compound. If poisoning is suspected, treatment should be symptomatic and supportive, paying particular attention to monitoring of respiratory and cardiac function. However, recovery is normally spontaneous. Do NOT use Atropine. Do NOT induce vomiting.

4.6 Adverse reactions (frequency and seriousness)

None at the recommended treatment rates.

4.7 Use during pregnancy, lactation or lay

This product may be used during pregnancy and lactation.
Do not use in sheep producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

As a spray for pigs and cattle or by spray or dip treatment for sheep.

Pigs: Mix at the rate of 40 ml 'Taktic' with every 10 litres of water. Prepare spray on the day of treatment, using clean water. Remove feed from pen and cover drinking bowls. Remove bedding and clean out pens. Treat all animals in a group at the same time, whether visibly affected or not. Use sufficient spray to soak animals thoroughly, paying particular attention to ears, groin and between the forelegs. Scabs need not be removed prior to treatment. During treatment spray walls, floors and fittings in the pen.

Recommended Control Programme

Initially treat the whole herd with Taktic. Repeat after 7 - 10 days. Make routine prophylactic treatment as follows:

Working Boars: Treat routinely every 2 - 3 months

Sows and Gilts: Treat as they enter farrowing quarters

Young Pigs: Treat after weaning or before moving to fattening houses

New additions to herd: Isolate and treat before mixing with other pigs

Buildings: To disinfect empty buildings, a single treatment of 80 ml Taktic with 10 litres water can be used

Cattle: Mix at the rate of 20 ml Taktic with every 10 litres of water. Prepare spray on the day of treatment, using clean water. Spray each animal depending on its live weight with 5 - 10 litres. Spray the whole body of the animal until it is thoroughly wet. In severe cases of mange and lice repeat the treatment after 7 - 10 days. In order to maintain the herd free from mange and lice, it is advisable to carry out regular routine treatments. Treat all animals in a group whether visibly affected or not. For control of ticks, cattle should be treated every 9 - 10 days during the period of risk.

Sheep: For ticks, lice, keds and mange mites including sheep scab, all sheep at risk should be treated. A single treatment will kill ticks and provide protection against reinfestation for up to 6 weeks. For lice and keds treatments should be repeated after 14 days and thereafter, if signs of reinfestation appear. Taktic is approved for control of sheep scab in a single dipping. Taktic has no strong odour - does not cause mis-mothering.

INITIAL CONCENTRATION: Mix at the rate of 1 litre Taktic with every 250 litres of water. Topping up: Mix at the rate of 1.5 litres Taktic with every 250 litres of water added. Do not allow the volume in the dip to drop by more than 10 % of the original volume before topping up.

METHOD: Prepare the dip on the day of dipping. Fill the bath with clean water. Add
the required amount of Taktic directly into the water in the bath and mix thoroughly by stirring well. Dip wash must be used on the day of preparation and must be discarded at the end of the day's dipping.

WHEN TO DIP: Adult sheep should be dipped immediately before ticks are expected to appear. Growing sheep should be dipped before being introduced to the tick infested land. Lambs can be safely dipped from 3 - 4 days of age and should be re-dipped after 3 to 4 weeks as the short fleece cannot hold sufficient dip to give prolonged protection. Allow sheep to rest and satisfy thirst before dipping. Sheep should be held in the dip wash for 1 minute immersing the head at least once.

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

In the unlikely event of accidental overdose, sedation may be observed. Natural recovery can normally be expected without clinical intervention but if necessary, supportive therapy should be maintained until symptoms subside.

4.11 Withdrawal Period(s)

Cattle
Meat and offal: 4 days
Milk: 4 days

Pig
Meat and offal: 1 day

Sheep
Meat and offal: 24 days
Milk: Not to be used for human consumption

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, amitraz.
ATCvet code: QP53AD01

5.1 Pharmacodynamic properties

Amitraz is a parasiticide belonging to the formamidine group of insecticides. The principle mode of action is interaction with octopamine receptors in the central nervous system (CNS) of ectoparasites which induces increased neuronal activity, abnormal behaviour, detachment and death.

Amitraz has a variety of pharmacodynamic activities which are believed to contribute both to its biological efficacy and to the clinical signs of toxicity.

Amitraz is a contact insecticide/acaricide with extended residual activity, functioning as an agonist at octopamine receptors in the nerve synapses. This produces increased nervous activity leading to rapid detachment of parasites and their eventual mortality. This novel mode of action differs from other established insecticides e.g. organophosphates, carbamates and synthetic pyrethroids.

In mammals, the following activities have been reported:

i. Alpha-2-adrenoreceptor agonist:

This is the main activity responsible for most clinical signs.

ii. Weak inhibitor of serotonin receptors

iii. Weak H1 receptor antagonist

iv. Mono-amine oxidase inhibitor in vitro but not apparently in vivo

Clinical symptoms of toxicity include:

i. Signs of CNS depression e.g. drowsiness

ii. Reduced body temperature

iii. Reduced heart rate and blood pressure

iv. Increased blood sugar levels (alpha-2-adrenergic agonists are known to reduce insulin release, e.g. clonidine)

v. Delayed gastro-intestinal transit.

5.2 Pharmacokinetic properties

Dermal absorption of amitraz is relatively slow and achieves peak blood levels 24-72 hours after dosing. Less than 10 % of the total applied dose was absorbed during the first 12 hours of a study on pigs.

Metabolism appears to follow the same route in all mammals observed to date.

Initial hydrolysis of amitraz is to N-(2,4-dimethylphenyl)-N'-methylformamidine (BTS 27271) and 2,4-dimethylformanilide (BTS 27919). The main end-products of metabolism are excreted predominantly in the urine and consist of 2-methyl-4-carboxyformanilide (BTS 39098), 4-acetamido-3-methylbenzoic acid (FBC 31158), their respective conjugates and conjugates of 4-amino-3-methylbenzoic acid (BTS 28369).

All these products may be converted to BTS 28369 by acid hydrolysis during extraction and processing. Excretion has been rapid following oral dosing in all species studied, with urine as the major route, accounting for 65 - 84 % of the dose (55 - 76 % in the first 24 hours).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tetra isopropyldiphenylcarbodiimide (Staboxol 1)
Nonyl phenol-ethylene oxide condensate (Ethylan KEO)
Solvesso 200

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
In-use shelf-life: Make up wash immediately before use. Any remaining product should be discarded.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Protect from frost.
Store in the original container tightly closed.

6.5 Nature and composition of immediate packaging

1 litre and 5 litre co-extruded PA/HDPE bottle with polyethylene screw cap. Not all pack sizes may be marketed.

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

WARNING
Harmful to fish. Do not contaminate ponds, waterways or ditches. Empty containers thoroughly and dispose of safely. Do not re-use empty containers.
Used dip should either be stored in a suitable holding tank prior to disposal by a reputable specialist contractor or it may be spread onto suitable land where there is no risk of pollution to ground or surface water.
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

Intervet Ireland Limited,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/125/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th september 2009

10 DATE OF REVISION OF THE TEXT