

**IRISH MEDICINES BOARD ACT 1995, as amended**

**European Communities (Animal Remedies) (No. 2) Regulations 2007**

VPA: **10007/017/001**

Case No: 7007714

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:

**Boehringer Ingelheim Ltd**

**Ellesfield Avenue, Bracknell, Berkshire RG12 8YS, 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:

**Mederantil 0.2 mg/ml Solution for Injection for cattle**

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation, unless revoked, shall continue in force from **03/09/2010**.

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

Mederantil 0.2 mg/ml Solution for Injection for cattle

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

##### **Active Substance**

Brotizolam 0.2 mg

##### **Excipients**

Propylene glycol 1.0378 g

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Solution for injection.

A clear, almost colourless solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Cattle

##### 4.2 Indications for use, specifying the target species

To stimulate the appetite in cattle where this is considered to be beneficial, either alone or as an adjunct to therapy for primary disease. For example, in metabolic disturbances (acetonaemia etc.), disorders in the puerperium, mastitis, inappetence, indigestion, diseases of the gastrointestinal tract, diseases of the respiratory organs, after surgery and changes in feed.

##### 4.3 Contraindications

Do not use as an alternative to causal therapy of clinical conditions.

Do not use in conditions where eating is likely to have a detrimental effect.

##### 4.4 Special warnings for each target species

Depending on the dosage and the general state of health, sedation may occur. This is substance-related and generally subsides rapidly. Once the sedation has subsided the appetite is stimulated. Too rapid intravenous injection may lead to a transient collapse. Onset of action is 1-10 minutes following intravenous injection. For animals whose prognosis is generally poor, stimulation of the appetite cannot be expected.

## 4.5 Special precautions for use

### Special precautions for use in animals

To avoid side effects, Mederantil should be injected slowly into the vein and at approximately body temperature. At first signs of intolerance the injection should be discontinued and, if necessary, treatment given for shock.

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

None.

## 4.6 Adverse reactions (frequency and seriousness)

A slight and transient sedation may be observed immediately after intravenous injection.

## 4.7 Use during pregnancy, lactation or lay

There is inadequate evidence of the safety of this product in pregnancy. Therefore, this product should only be used in pregnant animals where the expected benefit is thought to outweigh any risk to the foetus.

## 4.8 Interaction with other medicinal products and other forms of interaction

The sedative effect of Mederantil may be potentiated by other psychoactive compounds such as tranquilizers, sedatives or morphine-like analgesics.

## 4.9 Amounts to be administered and administration route

Mederantil 0.2 mg/ml Solution for Injection should be given by slow intravenous injection.

Heifers, bulls, cows 0.2 mg/100 kg bodyweight (1 ml/100 kg)

Weakened animals 0.16 mg/100 kg (0.8 ml/100 kg).

Calves (up to 100 kg bodyweight) 0.15-0.2 mg/100 kg (0.75-1 ml/100 kg).

A single injection is usually sufficient but if necessary the injection can be repeated after 12 hours.

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

Dosages up to 5 times the recommended dose may cause transient sedation, stumbling, unsteadiness and in rare cases increases of respiratory rate, increased salivation and coughing.

## 4.11 Withdrawal Period(s)

Meat and offal: zero days.

Milk: zero hours.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Benzodiazepine derivatives

ATC vet code: QN05CD09

## 5.1 Pharmacodynamic properties

Mederantil 0.2 mg/ml Solution for Injection is a benzodiazepine derivative which acts on specific receptors in the hunger centres of the hypothalamus to produce an orexigenic effect in cattle.

In an extensive clinical trial in cattle suffering from lack of appetite or diseases accompanied by lack of appetite very pronounced appetite stimulation was achieved with Mederantil 0.2 mg/ml Solution for Injection. This effect was particularly striking after intravenous injection.

## 5.2 Pharmacokinetic properties

### Absorption

Since Mederantil is to be used intravenously, Brotizolam is completely bioavailable.

### Distribution

Tissue levels of radioactivity were low in all tissues even as early as 6.5 h after dosing with the relatively highest level of parent drug and metabolites in liver.

### Metabolism

Brotizolam is metabolised by ringoxidation or oxidation of the methyl group followed by conjugation in Phase II metabolism.

### Elimination

Following a single intravenous dose, over 90% of the dose was recovered in excretion within 24 h, with faeces being the major route of excretion (70%, versus 24% of the dose in urine). The parent substance and metabolites were initially rapidly eliminated from plasma with a half-life of 0.5-1 h (up to 3 h post dosing) followed by a slower second elimination phase ( $T_{1/2}$  5 h), resulting in insignificant levels at 36 h after dosing.)

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Propylene glycol

### 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 medicinal product as packaged for sale: 5 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

Amber type II (Ph. Eur.) glass vials with a grey bromobutyl rubber bung containing 10ml solution.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Limited,  
Ellesfield Avenue,  
Bracknell,  
Berkshire,  
RG12 8YS,  
United Kingdom.

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10007/017/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

3rd September 2010

## **10 DATE OF REVISION OF THE TEXT**