

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridect Pour-On

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active Substance

Permethrin (cis: trans 80:20)                      4 % w/v

##### Excipient

Butyl Dioxitol

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Pour-on solution

A clear, straw coloured solution for topical administration.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Cattle.

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

Ridect is indicated for the following:

The control of flies on cattle.

The control of lice on cattle.

The treatment of chorioptic and sarcoptic mange.

Ridect is particularly effective against biting flies and horn flies and sucking and biting lice.

##### 4.3 Contraindications

Ridect should not be used in cattle under 1 week old.

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

None.

## 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

Its use as recommended should not present a hazard to operators provided they observe the following precautions:

Wear protective clothing, rubber gloves and boots when applying the product.

Wash splashes from the skin and eyes immediately.

When using the product do not eat, drink or smoke.

Wash hands and exposed skin before eating, drinking or smoking and after work.

Apply the product in a well ventilated area, preferably in the open air. Do not inhale the vapour.

## 4.6 Adverse reactions (frequency and seriousness)

None known.

## 4.7 Use during pregnancy, lactation or lay

Ridect may be used safely in pregnant or lactating cows.

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

None known.

## 4.9 Amounts to be administered and administration route

Ridect is designed for direct application to the top of the head and along the mid-line of the neck and back.

### *Dosage rate*

The recommended dose for all indications is 10 ml/100 kg bodyweight.

<u>Bodyweight</u>	<u>Dose Volume (ml)</u>
Calves up to 100 kg	10
101 to 200 kg	20
201 to 300 kg	30
over 300 kg	40

Ridect can be applied using the incorporated measure. Approximately a quarter of the calculated dose should be applied to the top of the head, the remainder should be poured along the neck and mid-backline.

Flies - A single dose is normally sufficient to control flies for 5 to 8 weeks. The first treatment should be carried out when the number of flies starts to increase. As with all insecticides, the degree of fly killing activity afforded by Ridect is influenced by prevailing weather conditions and the species of flies involved. In cases of heavy infestation, the dose may be repeated at 4 week intervals.

Lice - A single dose is normally sufficient to control all lice. In certain conditions of heavy challenges, the dose may be repeated after 4 weeks.

Mange - Apply Ridect Pour-On to all visibly affected areas : the remainder of the calculated doses should be applied along the backline. Mange infestation is most common on the rump and tailhead area and it is recommended that Ridect be applied to these areas in addition to any visible lesions. Repeat the dose after 4 weeks.

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

Ridect is well tolerated by cattle. No adverse effects are likely to be seen following an accidental overdose. Toxic signs in mammals include tremors, hypersensitivity, salivation, choreoathetosis and paralysis. The signs disappear rapidly and the animals recover, generally within a week. There is no specific antidote but symptomatic therapy can be given if considered necessary.

#### **4.11 Withdrawal Period(s)**

Treated animals must not be slaughtered for human consumption for a period of seven days immediately after treatment.

Milk withholding time is zero hours. However, it is recommended that cattle producing milk for human consumption should be treated immediately after milking, to allow as long an interval as possible (at least 6 hours) before the next milking.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Ridect is a pyrethroid insecticide active by contact and with good persistence. It is of low mammalian toxicity.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Butyl Dioxitol

#### **6.2 Incompatibilities**

None known.

#### **6.3 Shelf-life**

24 months.

#### **6.4 Special precautions for storage**

Do not store above 25°C.  
Store in original containers, tightly closed, in a safe place.

#### **6.5 Nature and composition of immediate packaging**

Ridect is supplied in 500ml or 1 litre twin neck high density polythene bottles incorporating two screw capped openings for filling and for a graduated dose measure. A heat seal is applied to both openings which are then fitted with compression caps.

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

Harmful to fish.

Do not contaminate ponds, waterways and ditches with the product or used containers.

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**

Pfizer Healthcare Ireland,  
Trading as Pfizer Animal Health,  
Ringaskiddy,  
Co. Cork,  
Ireland.

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10019/48/1

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

1<sup>st</sup> October 2004