

**IRISH MEDICINES BOARD ACT 1995**

**ANIMAL REMEDIES REGULATIONS, 2005**

**(S.I. No. 734 of 2005)**

VPA: **10900/012/001**  
Case No: 7001755

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

**Ark Animal Care Ltd**

**Newbridge, Co. Kildare, 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:

**Ark Iodine Spray**

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.

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

Ark Iodine Spray.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active Substance

Iodinated povidone 5 % w/v equivalent to 0.5 % w/v iodine.

##### Excipients

Isoproponol  
Purified water

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Cutaneous solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Farm animals.

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

For use as a general topical and quick drying antiseptic on farm animals in the prevention and control of infections susceptible to iodine.

##### 4.3 Contraindications

Do not use on cats.  
In rare instances of hypersensitivity discontinue treatment.

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

None.

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

Do not use near eyes or mucosa.

### **Special Precautions to be taken by the Person Administering the Medicinal Product to Animals**

Wash hands after use.

Not to be used by persons sensitive to iodine.

## **4.6 Adverse reactions (frequency and seriousness)**

None known.

## **4.7 Use during pregnancy, lactation or lay**

The product may be used in pregnant and lactating animals.

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

Do not mix with any other antiseptics or detergents.

## **4.9 Amounts to be administered and administration route**

Apply at full strength.

For topical use only.

Hold spray about six inches from the area to be treated. Press down plunger and spray thoroughly to cover the desired area. Allow to dry. The application may be repeated two or three times daily if required.

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

None known.

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

Edible tissues and milk: zero days.

## **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Povidine-iodine is an iodophore which is used as a general purpose antiseptic in a manner similar to iodine.

On contact with skin and mucous membranes, povidine-iodine slowly liberates iodine which diffuses into the microbial cell and produces its action by combining with the protein substances of the cell.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Isopropanol  
Purified Water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Two years.

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

Do not store above 25°C. Flammable. Keep away from heat and naked flame.

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

500 ml PVC container with pump spray mechanism.

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

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**

Ark Animal Care Ltd.,  
Newbridge Industrial Estate,  
Newbridge,  
Co. Kildare.

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

VPA 10900/12/1

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

1st October 2001