

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Thioxshield 40 mg/g Teat Dip Solution

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<b>Active substances</b>	<b>mg/g</b>
Benzyl alcohol.....	40
<b>Excipients</b>	
Patent blue V (E131).....	0.03
<b>Other Relevant Constituents</b>	
Glycerol.....	100

For full list of constituents, see section 6.1

### **3. PHARMACEUTICAL FORM**

Teat dip solution.  
A blue liquid

### **4. CLINICAL PARTICULARS**

#### **4.1 Target Species**

Cattle – milking cows

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

A ready to use teat dip as an aid in the control of bovine mastitis.

#### **4.3 Contraindications**

Not applicable

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

None

#### **4.5 Special precautions for use**

(i) Special precautions for use in animals

Wash and dry udders and teats before milking.  
Teat dip cups should be emptied after milking and washed before re-use.  
These are both important aspects of good hygiene and mastitis control.

For external use only.

- (ii) Special precautions for the person administering the veterinary medicinal product to animals

Do not eat, smoke or drink while using the product.

Wash hands and exposed skin after use.

Avoid contact with eyes. In the case of contact with eyes rinse with plenty of clean water and seek medical advice immediately.

Keep away from food, drink and animal feed.

Persons who are hypersensitive (allergic) to the ingredients in this product should handle the product with care.

- (iii) Other precautions

None

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

Very rare – change of active ingredient teat dip type can on very rare occasions cause skin irritation.

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

Can be used during pregnancy and lactation.

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

The use of the product has no known interactions with other products, including cow diet supplements.

Do not mix with other chemicals

#### **4.9 Amount(s) to be administered and administration route**

This product is used without dilution

##### Teat dipping:

Directly after milking each cow, dip the full length of each teat in the product. The teat cup should be kept topped up as necessary.

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

Not applicable for intended mode of application.

#### **4.11 Withdrawal period(s)**

Withdrawal period for meat/milk – zero days/hours.

## **5. PHARMACOLOGICAL PROPERTIES**

### **Pharmacotherapeutic group:**

Products for teats and udder, Disinfectants

**ATC Vet Code:** QG52A

Teat dips

### **5.1 Pharmacodynamic properties**

Benzyl alcohol teat dips have broad spectrum antibacterial action, against mastitis causative organisms. The microbiological action of benzyl alcohol appears to be due to protein denaturation and lipid dissolution.

### **5.2 Pharmacokinetic properties**

Benzyl alcohol is readily absorbed from the alimentary tract and rapidly oxidised to benzoic acid, which is conjugated with glycine and excreted as hippuric acid in the urine.

### **5.3 Environmental properties**

The impact of the active ingredient (benzyl alcohol) entering the environment via normal use of the product has been shown to be low.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Patent Blue V (E131)  
Glycerol  
Dodecyl Benzene Sulphonic Acid  
Phosphoric Acid  
Sodium Hydroxide  
Gum Xanthan  
Water Deionised

### **6.2 Incompatibilities**

Not to mix the product with other medical products.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

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

Do not store above 25°C  
Protect from direct sunlight  
Store in tightly closed original container

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

20 litre blue, white or natural opaque high density polyethylene drums with black high density polyethylene caps (screw fit, tamper evident, with expanded polyethylene gasket).

200 litre blue opaque high density polyethylene drums with white high density polyethylene caps (screw fit, with expanded polyethylene gasket.)

Not all pack sizes may be marketed.

The 200 litre container should not be returned for re-filling.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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**

Diversey Limited  
Weston Favell Centre  
Northampton  
Northamptonshire  
NN3 8PD

### **8. MARKETING AUTHORISATION NUMBER**

Vm 15985/4035

### **9. DATE OF FIRST AUTHORISATION**

12 October 2015

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

October 2015



Approved: 12 October 2015