

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Tolfedine Tablets 20mg

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

Each tablet contains:

Tolfenamic acid                      20mg

**For a full list of excipients, see section 6.1**

### **3. PHARMACEUTICAL FORM**

Tablet

White convex tablets, divisible in two.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs

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

Treatment for the alleviation of inflammation and pain and chronic locomotor disease in dogs.

**In small dogs** : in pathologies of osteoarticular and musculoskeletal systems.

#### **4.3 Contra-indications**

Do not administer to animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia or hypersensitivity to the product.

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

Long term treatment of over 3 months duration should be under regular veterinary supervision. In particular, dogs with hepatic insufficiency should be closely monitored.

See also 4.5

## **4.5 Special precautions for use**

### **(i) Special precautions for use in animals**

Use in animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided, animals may require a reduced dosage and careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Concurrent administration of potential nephrotoxic drugs should be avoided.

It is preferable that the product is not administered to animals undergoing general anaesthesia until fully recovered.

Do not exceed the prescribed dosage or duration of treatment.

Animals suffering from a chronic renal insufficiency and requiring an anti-inflammatory treatment may be treated with Tolfenamic acid without requiring an adjustment of the dosage. However, the use of this product is contra-indicated in acute cases of renal insufficiency.

In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during the treatment, your veterinarian should be contacted for advice.

### **(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

In case of accidental contact with eyes, wash with plenty of water.

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

Diarrhoea and vomiting may occur in rare cases during the treatment. Moreover, a temporary increase of thirst and/or diuresis may occur. In most of the cases, these signs cease spontaneously after the treatment.

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

Although studies in laboratory animals did not show any effect on reproduction, it is not advisable to administer the product during gestation.

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

Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Do not administer in conjunction with glucocorticosteroids.

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

4mg Tolfenamic acid/kg once daily, i.e. 1 tablet for 5kg of bodyweight administered in feed for 3 days according to the following table:

Weight of the animal (kg)	Number of tablets
4-6	1
6-8	1½
8-10	2
10-12.5	2½
12.5-15	3

Subject to clinical response, the administration may be repeated every 7 days, ie 3 days of medication followed by 4 days without medication.

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

In case of overdose, administer symptomatic treatment.

#### 4.11 Withdrawal period(s)

Not applicable

### 5. PHARMACOLOGICAL PROPERTIES

Tolfenamic acid (N-(2-methyl-3-chlorophenyl) anthranilic acid) is a non-steroidal anti-inflammatory drug belonging to the fenamate group. Tolfenamic acid possesses anti-inflammatory, analgesic and antipyretic properties.

The anti-inflammatory activity of Tolfenamic acid is due to inhibition of cyclooxygenase leading to a reduction in prostaglandin and thromboxane synthesis, major inflammatory mediators.

#### Pharmacokinetic properties:

##### Absorption :

Tolfenamic acid is rapidly absorbed. After a single oral administration of 4mg/kg Tolfenamic acid, the mean maximal plasma concentration (C<sub>max</sub>) of about 4µg/ml is reached in about 1 hour. When the same intake of Tolfenamic acid is taken with food, C<sub>max</sub> is 1.9 ± 1.4µg/ml. These variations are due to a strong enterohepatic recycling of the product.

##### Distribution, metabolism, excretion

Tolfenamic acid is distributed in all organs with a strong concentration in plasma, digestive tract, liver lungs and kidneys. The concentration in the brain however is low.

Tolfenamic acid and its metabolites do not cross the placenta barrier to any great extent.

Tolfenamic acid is excreted mainly unchanged.

In dogs with renal insufficiency, the elimination of Tolfenamic acid is unchanged.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Calcium Hydrogen Phosphate Dihydrate  
Wheat Starch  
Docusate Sodium  
Microcrystalline Cellulose  
Magnesium Stearate

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packages for sale 3 years.

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

Do not store above 25°C  
Store in a dry place

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

Box of 1 PVC – aluminium blister of 8 tablets  
Box of 2 PVC-aluminium blisters of 8 tablets  
Box of 12 PVC-aluminium blisters of 8 tablets  
Box of 24 PVC-aluminium blisters of 8 tablets  
Box of 48 PVC-aluminium blisters of 8 tablets

Not all pack sizes may be marketed.

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

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**

Vétoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr Alderton  
Towcester  
Northamptonshire  
NN12 7LS  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

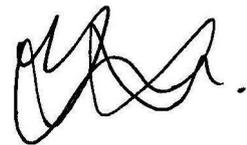
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**9. DATE OF FIRST AUTHORISATION**

15 October 1993

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

October 2023

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 13 October 2023