

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TUDOMAX, 10 mg/g, powder for use in drinking water/milk

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

### Active substances:

Bromhexine ..... 10.00 mg  
(As bromhexine hydrochloride 10.98 mg)

### Excipients:

Qualitative composition of excipients and other constituents
Citric acid
Silica, colloidal anhydrous
Lactose monohydrate

White or cream coloured powder.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle (calves), pigs, chickens, turkeys and ducks.

### 3.2 Indications for use for each target species

Mucolytic treatment of congested respiratory tract.

### 3.3 Contraindications

Do not use in cases of pulmonary oedema.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

In case of serious lungworm infection, the product should only be used 3 days after the commencement of the anthelmintic treatment.

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

This product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to bromhexine or to any of the excipients should avoid contact with the product.

This product may cause irritation of the respiratory and gastrointestinal tracts if accidentally ingested or inhaled.

During preparation and administration inhalation of dust particles should be avoided.

Wear an appropriate dust mask (either a disposable half-mask respirator conforming to European Standard EN149) or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), when handling the product.

This product may cause irritation to the skin, eyes and mucous membranes. Avoid direct contact with the product. Wear gloves and protective glasses during the use of the product.

If accidental contact occurs, rinse the affected area with large amounts of clean water. If symptoms develop following cutaneous, oral or inhalation exposure, seek medical advice and show this warning to the physician. Do not eat, drink or smoke while handling this product.

Wash hands and any exposed skin after use.

#### Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

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

Studies in laboratory animals have not produced evidence of foetotoxic effects or effects on fertility at the recommended dose. However this has not been specifically studied in the target species. Use only according to the benefit-risk assessment of the responsible veterinarian.

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

The product may be used in conjunction with antibiotics and/or sulphonamides and bronchodilators. Bromhexine modifies the distribution of antibiotics in the animal and increases their concentration in the serum and in the nasal secretions (e.g. spiramycin, tylosin and oxytetracycline). When administered concomitantly with the product, antimicrobial agents should, nevertheless, not be underdosed.

### **3.9 Administration routes and dosage**

Oral use. For use in in drinking water, milk or liquid feed.

0.45 mg of bromhexine per kg bodyweight, equivalent to 0.45 g of powder per 10 kg bodyweight, administered daily for 3 to 10 days, in drinking water, milk or liquid feed.

The following formula may be used to calculate the required concentration of product (in milligrams of product per litre drinking water):

$$\frac{45 \text{ mg veterinary medicinal product per kg bodyweight per day} \times \text{Average bodyweight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{mg of veterinary medicinal product per litre of drinking water}$$

In order to obtain the correct dosage the concentration of bromhexine has to be adjusted accordingly. The required amount of product should be weighed as accurately as possible using suitably calibrated

weighing equipment. The intake of medicated water, milk and liquid feed depends on the clinical condition of the animals.

When administering in liquid feed, first dissolve the product in water and then add feed. The preparation should be used immediately. Care should be taken that the intended dose will be completely ingested.

Any unused medicated water should be discarded after 24 hours.

The solubility of the product has been tested at the maximum concentration of 45 g/L at 20°C and at 5°C, a fine suspension may be observed.

Milk should be heated to feeding temperature prior to addition of the powder. The medicated milk should be freshly prepared prior to use and used within 3 hours.

### **FOR PROPORTIONER:**

When using a water proportioner, adjust the pump between 1% to 5% and adapt the volume of preparation accordingly.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

None known.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

#### Cattle (calves):

Meat and offal: 2 days.

Not authorised for use in animals producing milk for human consumption.

#### Pigs:

Meat and offal: Zero days.

#### Chickens, turkeys and ducks:

Meat and offal: Zero days.

Not for use in birds producing eggs for consumption, during and 4 weeks before the laying phase.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code :**

QR05CB02.

### **4.2 Pharmacodynamics**

Bromhexine is a mucoregulator. By activating the secretion of the seromucous glands, bromhexine helps to re-establish the viscosity and elasticity of bronchial secretions in the tracheobronchial tree. In addition, its expectorant action encourages mobilisation of mucus and enables effective bronchial drainage, thereby improving the functioning and defence capability of the lung.

These two simultaneous actions lead to an abundant discharge and facilitate a productive cough.

It breaks down the network of acid glycoprotein fibres found in mucoid sputum, which are mainly responsible for the characteristic viscosity.

### **4.3 Pharmacokinetics**

#### Absorption:

In pigs, bromhexine is rapidly absorbed after oral administration; peak plasma concentration occurs within one to three hours.

The concentration plateau is reached 12 hours after the second or third administration.

In calves, the plasma concentrations gradually increase over several hours after administration.

In turkeys or broilers, the peak plasma concentrations are achieved within 2-4 hours after oral administration of bromhexine.

#### Distribution:

Due to the lipophilic character of bromhexine, the parent compound has a strong affinity for lipid tissues and a slow depletion profile from these tissues.

#### Metabolism:

Bromhexine is extensively metabolised to more polar compounds.

#### Elimination:

The apparent half-life of elimination of total plasma radioactivity after the last dose is 20 to 30 hours in pigs, 40 to 50 hours in calves and 40 to 50 hours in chickens and turkeys.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water or liquid feed containing biocidal products, feed additives or other substances used in drinking water.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### **5.2 Shelf life**

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

Shelf life after first opening the immediate packaging: 3 months.

Shelf life after dilution in water according to directions: 24 hours.

Shelf life after dilution in milk according to directions: 3 hours.

### **5.3 Special precautions for storage**

This veterinary medicinal product does not require any special temperature storage conditions.

Keep the bags tightly closed.

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

Polyethylene/aluminium/polypropylene thermosealed bags.

#### Pack sizes:

1 kg.

500 g.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

S.P. VETERINARIA, S.A.

**7. MARKETING AUTHORISATION NUMBER(S)**

VPA10790/011/001

**8. DATE OF FIRST AUTHORISATION**

10/02/2017

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

10/03/2025

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

