Summary of Product Characteristics

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 substance:

Bromhexine	10.00 mg
(As bromhexine hydrochloride	10.98 mg)

Excipients:

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for use in drinking water/milk
White or cream coloured powder

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Calves), pigs, chickens, turkeys and ducks

4.2 Indications for use, specifying the target species

Mucolytic treatment of congested respiratory tract.

4.3 Contraindications

Do not use in case of pulmonary oedema.
In case of serious lungworm infection, the drug should only be used 3 days after the commencement of the anthelmintic treatment.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
See section 4.11

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 lactose should avoid contact with the product. 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. If respiratory symptoms develop following exposure, seek medical advice and show this warning to the physician.
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. Wash hands and any exposed skin after use. If accidental contact occurs, rinse the affected area with large amounts of clean water.

Do not eat, drink or smoke while handling this product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

The product may be used in conjunction with antibiotics and/or sulphonamides and bronchodilators.
When administered simultaneously with some antibiotics (e.g. oxytetracycline, spiramycin and tylosin), bromhexine has been shown to increase their concentration in the serum and in the nasal secretions. However, the significance of this finding is uncertain.

4.9 Amounts to be administered and administration route

For oral administration.

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):

$$\frac{\text{45 mg of the product per kg body weight and per day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{..... mg of the product per litre of drinking water}$$

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.

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

Unknown.

4.11 Withdrawal period(s)

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

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Expectorants except combinations with cough suppressants, mucolytics.

ATCvet code: QR05CB02.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, anhydrous
Silica, colloidal anhydrous
Lactose monohydrate

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bags tightly closed.

6.5 Nature and composition of immediate packaging

Polyethylene/aluminium/polypropylene thermosealed bags of 1 kg and 500 g

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.
Ctra. Reus - Vinyols Km 4, 1
Riudoms 43330
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10790/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 2017

10 DATE OF REVISION OF THE TEXT

December 2018