ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

500 g bags
1 kg bags

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Bromhexine	10.00 mg
(As bromhexine hydrochloride	10.98 mg)

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

500 g
1 kg

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 3 months
Use by…

[PL: Termin ważności (EXP)]

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

[PL: "Wyłącznie dla zwierząt. Wydawany z przepisu lekarza – Rp.

Do podawania pod nadzorem lekarza weterynarii."]

[NI: „POM-V"]

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.
Ctra. Reus
Vinyols Km 4, 1 Aptdo. 60
43330 Riudoms
Espana (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36967/4006

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

[PL: "Nr serii"]

B. PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE , IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

SP Veterinaria, S.A.
Ctra. Reus
Vinyols Km 4, 1 Aptdo. 60
43330 Riudoms
Espana (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Bromhexine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each g contains:

Bromhexine 10.00 mg
(As bromhexine hydrochloride 10.98 mg)

4. INDICATION(S)

Mucolytic treatment of congested respiratory tract.

5. 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.

6. ADVERSE REACTIONS

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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):

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.
Do not use this veterinary medicinal product after the expiry date stated on the label. The expiry date refers to the last day of that month.
Once opened, use by …….'

12. SPECIAL WARNINGS

Special warnings for each target species:

None.

Special precautions for use in animals:

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.

Pregnancy/Lactation/Lay /Fertility:

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.

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.

Overdose (symptoms, emergency procedures, antidotes):

None known.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

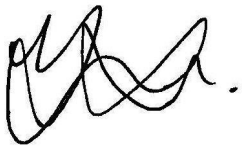
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

Package size:
500 g bag
1 kg bag

Not all pack sizes may be marketed.



Approved: 10 February 2022