ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE
PET/ALU/PE Bags of 1 kg/ 100 g in a white HDPE container

PARTICULARS TO APPEAR ON OUTER PACKAGE
Cardboard box (10 x 100 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bromhex-Air forte 25 mg/g oral powder for cattle, pigs, chickens, turkeys and ducks

Bromhexine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

1 g contains:

Active substance:

Bromhexine	22.775 mg
(equivalent to bromhexine hydrochloride	25mg)

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

1 kg

100 g
10 x 100 g

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
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 human consumption, during and 4 weeks before the laying period.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12. SPECIAL 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.

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

Pharmanovo Veterinärarzneimittel GmbH
Liebochstrasse 9
8143 Dobl
Austria

16. MARKETING AUTHORISATION NUMBER

Vm 52644/4000

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bromhex-Air forte 25 mg/g oral powder for cattle, pigs, chickens, turkeys and ducks

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

Marketing authorisation holder:
Pharmanovo Veterinärarzneimittel GmbH
Liebochstrasse 9
8143 Dobl
Austria

Manufacturer responsible for batch release:
AniMed Service AG
Liebochstrasse 9
8143 Dobl
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bromhex-Air forte 25 mg/g oral powder for cattle, pigs, chickens, turkeys and ducks

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

1 g contains:

Active substance:

Bromhexine	22.775 mg
(equivalent to bromhexine hydrochloride	25 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

None known.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For use in drinking water, liquid feed and dry feed in pigs
For use in drinking water in calves, chickens, turkeys, ducks

0.45 mg of bromhexine per kg bodyweight daily, equivalent to 1 g powder per 50 kg bodyweight administered for 3 to 10 consecutive days.

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

$$\frac{\text{20 mg of the product per kg bodyweight per day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{…mg of the product per litre drinking water}$$

The required amount of product should be weighed as accurately as possible using suitably calibrated weighing equipment. The intake of medicated water/milk replacer depends on the clinical condition of the animals.

Recommendation for dilution:

- Prepare a relevant quantity of water in a container.
- Add the product to the water while stirring the solution.
- Prepare the solution with fresh water immediately before use.

Solubility in water varies depending on temperature and water quality. Under worst case conditions (5 °C and hard water) a maximum solubility of approximately 151 g/L has been confirmed.

When using a proportioner, adjust flow rate settings of the dosing pump and adapt the volume of preparation accordingly depending upon water intake of animals to be treated.

When using a water tank, it is recommended to prepare a stock solution and to dilute it to the target final concentration. Turn off the water supply to the tank until all the medicated solution is consumed.

The time required for complete dissolution is less than 10 minutes.

Any unused medicated water should be discarded after 24 hours.

Instructions for use in feed (pigs):
Care should be taken that the intended dose will be ingested completely.
Medicated feed should be used immediately.
In feed use shall be restricted to individual treatment or for treatment of a small group/herd of animals.

Dry feed:
Before each administration the powder should be thoroughly mixed into a small amount of feed and should be given directly to the animal before the main ratio. Care should be taken to ensure complete consumption of all medicated feed prior to providing the remained of the daily feed ratio.
Continuous free access to drinking water should always be ensured, in particular immediately after the meal.
Liquid feed:
Prepare a pre-solution with the required amount of product. Take sufficient quantity of water in order to not exceed a maximum concentration of 151 g product per litre water in that pre-solution. The pre-solution must then be mixed into the liquid feed. The liquid feed should be continuously stirred during the preparation and distribution to the animals.

9. ADVICE ON CORRECT ADMINISTRATION

Please refer to section “Dosage for each species, route(s) and method of administration”

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 2 days
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: zero days

Chicken, turkey and ducks:
Meat and offal: zero days
Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution according to directions: 24 hours
Shelf life after dilution in liquid feed/ dry feed according to directions: 24 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
In cases of serious lungworm infection, the drug 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 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 and lay:
Studies in laboratory animals have not produced evidence of fetotoxic 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 by 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 organism 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 or household waste.
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

15. OTHER INFORMATION

Pack sizes:

PET/ALU/PE bags of 1 kg.

100 g in a white HDPE container.
Cardboard box containing 10 x 100 g in a white HDPE container.

Not all pack sizes may be marketed.

Approved 23 July 2021