1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:

Bromhexine	22.775 mg
(equivalent to bromhexine hydrochloride	25 mg)

Excipients:

Qualitative composition of excipients and other constituents
Citric acid
Glucose monohydrate

White or almost white, crystalline 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 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 veterinary medicinal product may cause hypersensitivity reactions (allergy).
People with known hypersensitivity to bromhexine should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause irritation of the respiratory and gastrointestinal tracts if accidentally ingested or inhaled.
This veterinary medicinal product may cause irritation to the skin, eyes and mucous membranes.
Direct contact and inhalation of dust particles should be avoided during preparation and administration.

Personal protective equipment consisting of 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) gloves and protective glasses should be worn when handling the veterinary medicinal product.

In case of accidental contact, rinse the affected area with large amounts of clean water.
In case of cutaneous, oral or inhalation exposure followed by the development of symptoms, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not eat, drink or smoke while handling this veterinary medicinal 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

The safety of the veterinary medicinal product has not been established during pregnancy and lay in the target species.

Pregnancy:

Laboratory studies in laboratory animals have not produced evidence of foetotoxic effects or effects on fertility at the recommended dose. Use only according to the benefit-risk assessment by the responsible veterinarian.

Laying birds:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal 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.

3.9 Administration routes and dosage

Pigs: In drinking water use, in-feed use.

Calves, chickens, turkeys, ducks: In drinking water use.

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

Instructions for in drinking water use:

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

The required amount of veterinary medicinal product should be weighed as accurately as possible. The use of suitably calibrated measuring equipment is recommended. The intake of medicated water depends on the clinical condition of the animals.

Recommendation for dilution in drinking water:

- 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.

Once reconstituted in the drinking water, the solution is clear, colourless to slightly yellowish.

Any unused medicated water should be discarded after 24 hours.

Instructions for in-feed use (pigs):

Care should be taken that the intended dose will be ingested completely.
Medicated feed should be used immediately.
The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be effectively controlled.

Dry feed:
Before each administration the veterinary medicinal product 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 veterinary medicinal 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.

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:

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.
Do not use within 4 weeks before the start of the laying period.

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.
Bromhexine 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. A plateau concentration is not reached within a five-day treatment period.

In turkeys or chickens, the peak plasma concentrations are achieved within 2-4 hours after oral administration of bromhexine. A plateau concentration is not reached.

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

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

5.2 Shelf life

1 kg bag:

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

100 g container:

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.

1 kg bag, 100 g container:

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

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

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.

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.

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

Pharmanovo Veterinärarzneimittel GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10420/002/001

8. DATE OF FIRST AUTHORISATION

03/09/2021

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

16/06/2026

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).