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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bromhex-Air forte 25 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substances:

Bromhexine	22.775 mg
(equivalent to bromhexine hydrochloride	25 mg)

3. PACKAGE SIZE

10 x 100 g

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pigs: In drinking water use, in-feed use.
Calves, chickens, turkeys, ducks: In drinking water use.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened used within 3 months.
Once diluted in drinking water use within 24 hours.
Once diluted in liquid feed/ dry feed use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmanovo Veterinararzneimittel GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 52644/4000

15. BATCH NUMBER

Lot {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bromhex-Air forte 25 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substances:

Bromhexine	22.775 mg
(equivalent to bromhexine hydrochloride	25 mg)

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened used within 3 months.
Once opened use by: …
Once diluted in drinking water use within 24 hours.
Once diluted in liquid feed/ dry feed use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmanovo Veterinararzneimittel GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each g contains:

Active substances:

Bromhexine	22.775 mg
(equivalent to bromhexine hydrochloride	25 mg)

White or almost white, crystalline powder.

3. Target species

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

4. Indications for use

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. Special warnings

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 with skin, 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.

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

- *Pregnancy:*

  Laboratory Sstudies 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 by the responsible veterinarian.

- *Laying birds:*

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

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.

Overdose:
None known.

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system at:
Website:https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

Please refer to section “Dosage for each species, routes and method of administration”.

10. 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 or intended to produce eggs for human consumption.
Do not use within 4 weeks before the start of 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.

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 precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 52644/4000

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Pharmanovo Veterinararzneimittel GmbH
Liebochstrasse 9
Dobl
Dobl-Zwaring
Steiermark
8143
Austria

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

Local representatives and contact details to report suspected adverse reactions:
DUGV (UK) Limited
Union House 111, New Union Street
Coventry, CV1 2NT
United Kingdom
Tel: +353 (0) 504 43169

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {PET/ALU/PE Bags of 1 kg/ 100 g in a white HDPE container}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each g contains:

Active substances:
Bromhexine 22.775 mg
(equivalent to bromhexine hydrochloride 25 mg)
White or almost white, crystalline powder.

3. PACKAGE SIZE

1 kg
100 g
10 x 100 g

4. TARGET SPECIES

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

5. INDICATIONS FOR USE

Indications for use
Mucolytic treatment of congested respiratory tract.

6. CONTRAINDICATIONS

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.

7. SPECIAL WARNINGS

Special warnings
Special warnings:
None.

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 with skin, 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.

Pregnancy, lactation:
Laboratory 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 by the responsible veterinarian.

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.

Overdose:
None known.

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

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details on this label, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
Please refer to section “Dosage for each target species, routes and method of administration”.

11. WITHDRAWAL PERIODS

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 or intended to produce eggs for human consumption.
Do not use within 4 weeks before the start of the laying period.

12. SPECIAL STORAGE PRECAUTIONS

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52644/4000

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder <and contact details to report suspected adverse events>:
Pharmanovo Veterinararzneimittel GmbH
Liebochstrasse 9
Dobl
Dobl-Zwaring
Steiermark
8143
Austria

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

Local representatives and contact details to report suspected adverse reactions:
DUGV (UK) Limited
Union House 111, New Union Street
Coventry, CV1 2NT
United Kingdom
Tel: +353 (0) 504 43169

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

Other information

POM-V

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}
Once opened used within 3 months.
Once opened use by: …
Once diluted in drinking water use within 24 hours.
Once diluted in liquid feed/ dry feed use within 24 hours.

21. BATCH NUMBER

Lot {number}

Gavin Hall

Approved: 09 July 2026