*[Version 8.1,01/2017]*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bromhex-Air basic 10 mg/g oral powder for cattle, pigs, chickens, turkeys and ducks (BE, LU, NL)
Bromhex-Air basic oral powder for cattle, pigs, chickens, turkeys and ducks (FR)

Respirexin 10 mg/g oral powder for cattle, pigs, chickens, turkeys and ducks (AT)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains:

**Active substance:**

| | |
|---|---|
| Bromhexine | 9.11 mg |
| (equivalent to bromhexine hydrochloride | 10 mg) |

**Excipients:**
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral powder
White or almost white, crystalline 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 cases of pulmonary oedema.
Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

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.

## 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 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.

## 4.8 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.

## 4.9 Amounts to be administered and administration route

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 0.5 g powder per 10 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).

$$\frac{\text{50 mg of the product per kg bodyweight per day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{…mg of the product per litre drinking water}$$

The required amount of product should be weighed as accurately as possible using suitably calibrated weighing equipment. The intake of medicated water 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 248 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 248 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.

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

None known.

### 4.11 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

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.

## 5. PHARMACOLOGICAL PROPERTIES

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

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Citric acid
Glucose 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

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

### 6.4. Special precautions for storage

Do not store above 25 °C.

### 6.5 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.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Pharmanovo Veterinärarzneimittel GmbH
Liebochstrasse 9
8143 Dobl
Austria

## 8. MARKETING AUTHORISATION NUMBER(S)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

## 10 DATE OF REVISION OF THE TEXT

12/2022