# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bisolvon 10mg/g Oral Powder

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active Substance
Bromhexine Hydrochloride 10 mg
For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Powder for oral solution or addition to feed.
White crystalline powder.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, pigs, dogs and cats.

### 4.2 Indications for use, specifying the target species

As an aid to the treatment of respiratory disease in cattle, pigs, dogs and cats where mucus is a complicating factor.

### 4.3 Contraindications

Not for use in cows producing milk for human consumption.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

**Special precautions for use in animals**

None.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid contact with the skin and eyes. In case of accidental eye contact, flush the affected eye with copious amounts of clean running water. Wash hands and exposed skin after administering the product.

**4.6 Adverse reactions (frequency and seriousness)**

None known.

**4.7 Use during pregnancy, lactation or lay**

Not applicable.

**4.8 Interaction with other medicinal products and other forms of interactions**

May be used in conjunction with antibiotics and/or sulphonamides, bronchodilators etc.

**4.9 Amounts to be administered and administration route**

For oral administration in the feed or drinking water. Add to feed or drinking water immediately before administration. Discard any remaining medicated feed or drinking water.

| **Species** | **Total Daily Dose of bromhexidine hydrochloride (mg per kg)** | **Total daily dose in g of powder** | **Frequency** | **Duration of treatment (days)** |
|---|---|---|---|---|
| Cattle | 0.5 | 5g / 100 kg | Once daily | 5 |
| Pigs | 0.2-0.5 | 2-5 g / 100 kg | Once daily | 5 |
| Dogs | 2.0 | 2 g / 10 kg | Twice daily | 5 |
| Cats | 1.0 | 0.5 g / 5 kg | Once daily | 7 |

The 500 g and 1 kg pack contain a white measure, delivering approximately 5 g when filled level. The sachet pack contains blue measuring scoops delivering approximately 0.5 g when filled level, suitable for the small animal doses.

The following table illustrates dose to be administered at each treatment (once daily in cattle, pigs and cats and twice daily in dogs) on a per scoop basis.

| **Species** | **Bodyweight (kg)** | **Dose of Bisolvon Powder (g) at each treatment** | **No of white (5 g) scoops** | **No. of blue (0.5 g) scoops** |
|---|---|---|---|---|
| Calves<br><br>Cattle | 100<br><br>400 | 5<br><br>20 | 1<br><br>4 | |
| Pigs | 100 | 2-5 | ½ -1 | |
| Dogs | 5<br><br>15 | 0.5<br><br>1.5 | | 1<br><br>3 |
| Cats | 5 | 0.5 | | 1 |

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

Not applicable.

**4.11 Withdrawal period(s)**

Meat and offal:
Cattle: 2 days.
Pigs: zero days.
Not permitted for use in lactating cows producing milk for human consumption.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

ATCVet code: QR05CB02

Bisolvon is a mucolytic with two main pharmacological actions. Firstly it stimulates an increase in the secretion of fluid by the mucus glands of the respiratory tract. Secondly it breaks down the network of acid glycoprotein fibres found in mucoid sputum, which are mainly responsible for the characteristic viscosity. Bisolvon has

been shown to increase mucociliary clearance in calves suffering from respiratory disease.

When Bisolvon is administered simultaneously with oxytetracycline in cattle and pigs, the levels of the antibiotic in the bronchial mucus are increased by more than 40%. The clinical significance of this action is uncertain.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glucose Monohydrate

### 6.2 Major incompatibilities

None known.

### 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
If sachets are to be used over a period of a few days, they should be resealed as well as possible between doses. Discard any unused material.

### 6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place.
Keep the container in the outer carton.

### 6.5 Nature and composition of immediate packaging

Paper/aluminium foil laminate sachets (heat sealed) containing 5 g powder. Boxes of 40 sachets also contain 0.5 g blue polystyrene measuring spoons.

High density polyethylene jars with HDPE screw caps and PVC-faced cork wad containing 100 g or 500 g powder and a 5 g white polystyrene measuring spoon.
High density polyethylene jar with push-fit polyethylene cap containing 1000 g powder and a 5 g white polystyrene measuring spoon.

Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

## 7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/002/001

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

Date of first authorisation: 1st October 1991
Date of last renewal: 30th September 2006

## 10 DATE OF REVISION OF THE TEXT

November 2018