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
10 mg Bromhexine hydrochloride per gram
For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Oral powder.
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

None known.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

(i) Special precautions for use in animals

None known.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with 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 interaction

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.

Species	**Total Daily Dose of Bromhexine Hydrochloride (mg /kg)**	**Total Daily Dose in g of Powder**	**Frequency**	**Duration of treatment (days)**
Cattle	0.5	5 g/100 kg	Once daily	5
Pigs	0.2-0.5	2-5g/100 kg	Once daily	5
Dogs	2.0	2g/10 kg	Twice daily	5
Cats	1.0	0.5g/5 kg	Once daily	7

The 500 g and 1 kg pack contains 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 the 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 Cattle	100 400	5 20	1 4	
Pigs	100	2-5	½-1	
Dogs	5 15	0.5 1.5		1 3
Cats	5	0.5		1

4.10 Overdose (Symptoms, Emergency Procedures, Antidotes)

No treatment is specified.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

ATCVet code: QR05CB02
Summary Presentation of the active ingredient:
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 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale : 5 years
Shelf life after dilution or reconstitution according to directions: 24 hours
Shelf life after first opening the immediate packaging: 7 days

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place. 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 after 7 days. Discard any remaining medicated feed or drinking water which is not consumed within 24 hours.

6.5 Nature and composition of immediate packaging

Polyethylene/paper/aluminium foil laminate sachets (heat sealed) containing 5 g powder packed in boxes of 40 sachets with 0.5 g blue polystyrene measuring spoons.

100 g white high density polyethylene tub closed with white high density polyethylene screw-fit cap.
500 g white high density polyethylene tub closed with white high density polyethylene insert with polypropylene screw-fit cap.
1000 g white high density polyethylene container closed with white low density polyethylene push-fit cap.
The above three pack sizes come with a clear polystyrene spoon delivery approx 5g of powder.

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 material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4290

9. DATE OF FIRST AUTHORISATION

8 April 2004

10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 09 November 2018