

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Folding box (40 x 5 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bisolvon 10 mg/g Oral Powder
Bronchial Mucolytic

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g of Bisolvon Powder contains 10 mg bromhexine hydrochloride.

3. PHARMACEUTICAL FORM

Powder for oral solution or in-feed use.

4. PACKAGE SIZE

40 x 5 g

5. TARGET SPECIES

Cattle, pigs, dogs and cats.

6. INDICATION(S)

Bisolvon is a mucolytic for use as an aid to the treatment of respiratory disease in cattle, pigs, dogs and cats, where mucus is a complicating factor.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration in the feed or drinking water. See leaflet for details.

Species	Total Dose of Bromhexine Hydrochloride (mg /kg ⁻¹)	Total Daily Dose in g of Powder	Frequency	Duration of treatment (d)
Cattle	0.5	5 g/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 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 dose basis.

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

8. WITHDRAWAL PERIOD

Do not use in cows producing milk for human consumption. Cattle meat: 2 days; Pigs: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the leaflet before using the product.

Add to feed or drinking water immediately before administration. Discard any remaining medicated feed or drinking water which is not consumed within 24 hours. Do not use after the stated expiry date.

To be supplied only on veterinary prescription.

See leaflet for user warnings.

10. EXPIRY DATE

Expiry Date (Month/year)

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place. After opening a sachet use the contents over a period of a few days. If sachets are to be used over a period of few days, they should be resealed as well as possible between doses. Any unused material should be discarded within 7 days. Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product, medicated feed and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

FOR ANIMAL TREATMENT ONLY.

UK	POM-V
IE	POM

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

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 08327/4290

IE: VPA 10007/14/1

17. MANUFACTURER’S BATCH NUMBER

Batch No

SMALL IMMEDIATE PACKAGING UNITS

Sachet (5 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bisolvon 10 mg/g Oral Powder

Bronchial Mucolytic

Uses: Bisolvon is a mucolytic for use as an aid to the treatment of respiratory disease in cattle, pigs, dogs and cats, where mucus is a complicating factor.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Powder for oral solution or in-feed use.

Each gram of Bisolvon Powder contains 10 mg bromhexine hydrochloride.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 g

4. ROUTE(S) OF ADMINISTRATION

Add to feed or drinking water immediately before administration. Read the package leaflet before using the product.

5. WITHDRAWAL PERIOD

Not for use in cows producing milk for human consumption. Cattle meat: 2 days;
Pigs: zero days

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry Date (Month/year)

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY.

9. Other information

For full information, disposal advice and warnings, see leaflet.

Do not store above 25°C. Store in a dry place. Do not use after the stated expiry date. After opening a sachet use the contents within a few days and reseal as well as possible between doses. Discard any remaining medicated feed or drinking water, which is not consumed within 24 hours. Any unused material should be discarded within 7 days. Keep container in outer carton.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

To be used in accordance with the directions of a veterinary surgeon. To be supplied only on veterinary prescription. Do not use after the stated expiry date.

UK: VM 08327/4290

IRELAND: VPA 10007/14/1

Marketing Authorisation Holder

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer

Klocke Pharma-Service GmbH
D-77767 Appenweier
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bisolvon 10 mg/g Oral Powder

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each gram contains 10 mg bromhexine hydrochloride.
Powder for oral solution or in-feed use.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cattle, pigs, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 ⁻¹)	Total Daily Dose of Powder (g)	Frequency	Duration of treatment (d)
Cattle	0.5	5 g/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 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 dose basis:

Species	Bodyweight (kg)	Dose of Bisolvon Powder (g)	No. of 5 g sachets	No. of blue (0.5 g) scoops
Calves	100	5	1	
Cattle	400	20	4	
Pigs	100	2-5	½-1	
Dogs	5	0.5		1
	15	1.5		3
Cats	5	0.5		1

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Cattle meat: 2 days

Pigs: zero days.

Not for use in cows producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place.

Do not use after the expiry date stated on the label and carton.

After opening a sachet, use the contents within a few days and re-seal as well as possible between doses. Any unused material should be discarded within 7 days.

Discard any remaining medicated feed or drinking water which is not consumed within 24 hours. Keep container in outer carton.

To be supplied only on veterinary prescription.

When the container is broached (opened) for the first time, using the in-use shelflife which is specified on the package leaflet, the date on which any product remaining in the carton should be dis-carded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Operator Warnings

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.

For Animal Treatment Only

Keep out of the reach and sight of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product, medicated feed and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package Quantities

40 x 5 g sachets.

Further Information

May be used in conjunction with antibiotics and/or sulphonamides, bronchodilators etc. Bisolvon has been shown to increase mucocilliary 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.

Marketing Authorisation numbers

UK: Vm 08327/4290

Ireland: VPA 10007/14/1

Approved: 09 November 2018

