

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bisolvon 3mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Bromhexine Hydrochloride 3.0 mg

Excipients

Methyl Parahydroxybenzoate 0.7 mg

Propyl Parahydroxybenzoate 0.3 mg

Water for Injections to 1.0 ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A clear colourless sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and pigs.

4.2 Indications for use, specifying the target species

As an aid to the treatment of respiratory disease in cattle and pigs, 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

Care should be taken to avoid accidental self injection.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product may be given to pregnant and lactating animals.

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

Bisolvon injection should be administered once daily by intramuscular route.

Species	Dose of bromhexine hydrochloride	Dose of Bisolvon Injection	Frequency	Duration of treatment
Cattle	0.5 mg/kg	17 ml/100 kg*	once daily	5 days
Pigs	0.2-0.5 mg/kg	7-17 ml/100 kg*	once daily	5 days

*Maximum dose at one site: 20ml cattle; 10ml pigs.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal:

Cattle and pigs: 28 days

Not permitted for use in lactating cows producing milk for human consumption

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet code:QR05CB02

Summary presentation of the active ingredient:

Bisolvon is a mucolytic with two main pharmacological actions. Its first effect is to stimulate 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 its 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 considerably increased (by more than 40%). The clinical significance of this action is uncertain.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Tartaric Acid
Water for Injections

6.2 Incompatibilities

Do not dilute or mix with other compounds.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

Following withdrawal of the first dose, use the product within 28 days. Discard any unused material.

6.4 Special precautions for storage

Do not refrigerate or freeze.
Keep the vial in the outer carton.

6.5 Nature and composition of immediate packaging

Multidose amber glass (Type II Ph.Eur) injection bottles with grey bromobutyl siliconised rubber stoppers and aluminium crimp caps, containing 100 ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/015/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th Septemeber 2006

10 DATE OF REVISION OF THE TEXT

19th May 2009