

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimucin 2g, Oral Powder for Horses.
Acetylcysteine.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 sachet of 6g oral powder contains:

Active substance

Acetylcysteine 2000 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White to pale yellow oral powder

4 CLINICAL PARTICULARS

4.1 Target Species

Horse

4.2 Indications for use, specifying the target species

Reduction of viscosity of the tracheobronchial secretion in the supportive mucolytic treatment of chronic broncho-pulmonary diseases accompanied by abnormal secretion and mucostasis in the horse.

4.3 Contraindications

Do not administer the product in case of known hypersensitivity to acetylcysteine.
See also section 4.8.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The product should not be used in horses suspected of suffering from gastric ulceration.

As acetylcysteine is metabolised to sulphur containing products, use cautiously in horses known to be suffering from liver disease.

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

Persons should wear gloves during administration.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity to acetylcysteine may occur.
Should undesirable effects occur, withdraw the product and treat symptomatically.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic effect. Safety of the product has not been established during pregnancy and lactation. Use only accordingly to the risk/benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Acetylcysteine must not be combined with other medicinal products as incompatibilities may occur. Reports of inactivation of beta lactam antibiotics (penicillins and cephalosporins) and tetracyclines have so far referred to in-vitro tests in which the substances were directly mixed. An interval of at least 2 hours should be allowed to elapse before administering these antibiotics (this does not apply to doxycycline). Acetylcysteine is compatible with potentiated sulfonamides and all current bronchodilators and can be administered concomitantly. Concomitant administration with antitussives may lead to a hazardous build-up of secretion due to the restricted cough reflex. Combined treatment of the product and antitussives should therefore be avoided.

4.9 Amounts to be administered and administration route

In-feed use.
10 mg/kg bw acetylcysteine twice daily (total daily dose of 20 mg/kg bw), during 20 days.

Dosage scheme:

Horse weight	Recommended morning dose	Recommended evening dose
(kg body weight)	(Sachets Equimucin 2g, oral powder)	(Sachets Equimucin 2g, oral powder)
Up to 200 kg	1 sachet	1 sachet
Up to 400 kg	2 sachets	2 sachets
Up to 600 kg	3 sachets	3 sachets

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

Daily oral administration of 3 times the recommended treatment dose for a period of 4 weeks to horses was tolerated without undesirable effects.

4.11 Withdrawal Period(s)

Horses:
Meat and offal: zero days
Milk*: zero days

* To be considered in countries where horse milk is used for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Mucolytics

ATCvet code: QR05CB01

5.1 Pharmacodynamic properties

Acetylcysteine can reduce the viscosity of bronchial mucus through reductive breaking of the disulfide bridges of mucopolysaccharides and trigger a mucolytic effect following oral administration.

According to *in vitro* observations, acetylcysteine exerted protective effects due to the direct detoxification of toxins in the respiratory tract through reduction (e.g. of oxidising substances) and conjugation (e.g. formaldehyde). Free radicals can be bound and thus inactivated by the reactive SH group. These protective properties are not demonstrated *in vivo* at present.

5.2 Pharmacokinetic properties

Following oral administration to man, acetylcysteine is rapidly and virtually completely absorbed and metabolised in the liver into the endogenous amino acid, cysteine, the pharmacologically active metabolite, as well as diacetylcysteine, cystine and other combined disulfides and inorganic sulfate.

The bioavailability in man of orally administered acetylcysteine is very low due to the high first-pass effect (approximately 10%). Pharmacokinetic data in horses are not available at present.

In laboratory animals acetylcysteine and its metabolites are excreted almost exclusively in the form of inactive metabolites (inorganic sulfates, diacetylcysteine) via the kidneys. Inorganic sulfate is the principal excretion product in urine. Small quantities of unchanged acetylcysteine are always present in the urine as acetylcysteine is a physiological intermediate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose (Saccharose)

Vanillin

6.2 Incompatibilities

Acetylcysteine can lead to the *in-vitro* inactivation of antibiotics (see also section 4.8).

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

Sachet (LDPE/aluminium/LDPE/paper) with sealed edges containing 6 g oral powder.

Cardboard box of 100 sachets, each containing 6 g oral powder.

Cardboard box of 200 sachets, each containing 6 g oral powder.

Cardboard box of 500 sachets, each containing 6 g oral powder.

Not all pack sizes may be marketed.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH
Ostlandring 13
D - 31303 Burgdorf
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10810/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th August 2009

10 DATE OF REVISION OF THE TEXT

21st July 2010