SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimucin 2g, oral powder for horses

DK, FI, NO: Equimucin **Vet** 2g, oral powder for horses

Acetylcysteine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 sachet of 6 g 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 [kg body weight]	**Recommended morning dose** [Sachets Equimucin 2g, oral powder]	**Recommended evening dose** [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 were horse milk is used for human consumption.

5. PHARMACOLOGICAL 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 particulars

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%). Pharmakokinetic 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/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 product or waste materials derived from the use of such products

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)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

LABELLING AND PACKAGE LEAFLET

A. LABELLING

Label of the cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimucin 2g, oral powder for horses

DK, FI, NO: Equimucin **Vet** 2g, oral powder for horses

Acetylcysteine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 sachet of 6 g oral powder contains:

Active substance:

Acetylcysteine	2000 mg

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

Cardboard box of 100/200/500 sachets, each containing 6 g oral powder.

5. TARGET SPECIES

Horse.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horses:

Meat and offal:	zero days
Milk*:	zero days

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

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch:

Label of the sachets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimucin 2g, oral powder for horses

DK, FI, NO: Equimucin **Vet** 2g, oral powder for horses

Acetylcysteine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 sachet of 6 g oral powder contains:

Active substance:

Acetylcysteine	2000 mg

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

Sachet of 6 g oral powder.

4. ROUTE(S) OF ADMINISTRATION

In-feed use.

5. WITHDRAWAL PERIOD

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

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

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Equimucin 2g, oral powder for horses
DK, FI, NO: Equimucin **Vet** 2g, oral powder for horses

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

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

Manufacturer for the batch release:
Catalent Germany Schorndorf GmbH
Steinbeisstr. 1 & 2
73614 Schorndorf, Germany

Lindopharm GmbH
Neustrasse 82
40721 Hilden, Germany

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimucin 2g, oral powder for horses

DK, FI, NO: Equimucin **Vet** 2g, oral powder for horses

Acetylcysteine

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

1 sachet of 6 g oral powder contains:
Active substance:

Acetylcysteine	2000 mg

Excipients:
Sucrose, Vanillin

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not administer the product in case of known hypersensitivity to acetylcysteine.
See also section 12.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Horse.

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

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 [kg body weight]	**Recommended morning dose** [Sachets Equimucin 2g, oral powder]	**Recommended evening dose** [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

10. WITHDRAWAL PERIOD

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

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

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep out of the reach and sight of children.
Do not use after the expiry date stated on the sachets.

12. SPECIAL WARNING(S)

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.

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.

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.

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.

Incompatibilities
Acetylcysteine can lead to the *in-vitro* inactivation of antibiotics.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.