[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ancesol 10 mg/ml solution for injection for cattle
(AT, BE, BG, CZ, DE, EE, EL, ES, FI, IT, LT, LV, NL, PL, PT, RO, SI, SK)

Ancesol solution for injection for cattle
(FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Chlorphenamine maleate (equivalent to 7.03 mg chlorphenamine)	10 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.00 mg
Propyl parahydroxybenzoate	0.20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to almost colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For the symptomatic treatment of conditions associated with histamine release.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
Although intravenous administration has an immediate therapeutic effect, it can have excitatory effects on the CNS. Consequently, administer slowly and interrupt administration for a few minutes if necessary, when using this route. Do not administer via the subcutaneous route.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Accidental self-injection may result in sedation. Care should be taken to avoid accidental self-injection with this drug. Preferably use a guarded needle until the moment of injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE.
Wash splashes from skin and eyes immediately.

4.6 Adverse reactions (frequency and seriousness)

Chlorphenamine has a weak sedative effect.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only in accordance with the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Concomitant use of other antihistamines or barbiturates may boost the sedative effect of chlorphenamine. The use of antihistamines may conceal early signs of ototoxicity caused by some antibiotics (e.g. aminoglycoside and macrolide antibiotics) and may shorten the effect of oral anticoagulants.

4.9 Amounts to be administered and administration route

For intramuscular or slow intravenous use, see also section "4.5 Special precautions for use in animals".

Adult animals:
0.5 mg Chlorphenamine maleate/kg bodyweight (5 ml/100 kg bodyweight), once a day for three consecutive days.

Calves:
1 mg Chlorphenamine maleate/kg bodyweight (10 ml/100 kg bodyweight), once a day for three consecutive days.

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

Doses up to four times the therapeutic dose have been well tolerated. In very rare cases, local reactions were observed in the neck region at the injection site. All the reactions were transient and resolved spontaneously.

4.11 Withdrawal period(s)

Meat and offal: 1 day
Milk: 12 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antihistamines for systemic use. ATC vet code: QR06AB04

5.1 Pharmacodynamic properties

Chlorphenamine maleate is a racemic compound classified as an alkyl amine group antihistamine that, due to its chemical characteristics, is able to bind to the H1 receptor present on the cell membrane and therefore compete with the natural endogenous ligand for the same site. Receptor occupation by chlorphenamine maleate does not, in itself, induce pharmacological responses, but significantly inhibits those induced by histamine. On the basis of these observations, chlorphenamine maleate behaves as a direct or reversible competitive receptor antagonist. Chlorphenamine maleate is not able to inhibit the synthesis or release of histamine.

5.2 Pharmacokinetic particulars

After intravenous administration the plasma concentration of the active substance drops from 36 ng/ml to the method's limit of detection (1 ng/ml) 24 hours after administration. The elimination half-life ($T_{1/2\beta}$) is 2.11 hours, the mean residence time (MRT) is 2.35 hours, total clearance (Cl_B) 1.315 l/kg/h and the volume of distribution (V_d) just over 3 l/kg. Following intramuscular administration, peak concentration (C_{max} = 142 ng/ml) is reached in 28 minutes (T_{max}). Plasma concentrations then drop rapidly to reach values of 60 and 12 μg/kg after 2 and 8 hours before dropping below the limit of quantification (1 μg/kg) 24 hours after treatment. MRT and bioavailability were 3.58 hours and 100%, respectively.
The compound and its metabolites are excreted primarily via the kidneys in urine, with a small amount in unmodified form and the majority as a breakdown product, almost completely, within 24 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Sodium dihydrogen phosphate dihydrate
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

After first opening do not store above 30 °C.

6.5 Nature and composition of immediate packaging

Amber glass vial, type II (Ph.Eur.) with bromobutyl-rubber stopper type I (Ph.Eur.) and aluminium cap in a cardboard box.
Package sizes: 1 x 100 ml, 5 x 100 ml
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 materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Richter Pharma AG
Feldgasse 19
4600 Wels
AUSTRIA

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
Date of last renewal: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 1 x 100 ml, 5 x 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ancesol 10 mg/ml solution for injection for cattle
(AT, BE, BG, CZ, DE, EE, EL, ES, FI, IT, LT, LV, NL, PL, PT, RO, SI, SK)

Ancesol solution for injection for cattle
(FR)

Chlorphenamine maleate

2. STATEMENT OF ACTIVE SUBSTANCES

Chlorphenamine maleate 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
5 x 100 ml

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or slow intravenous administration.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 1 day
Milk: 12 hours

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

EXP {month/year}
Once broached, use by 28 days.

11. SPECIAL STORAGE CONDITIONS

After first opening do not store above 30 °C.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Richter Pharma AG, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

XXXX

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml amber glass vial, type II.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ancesol 10 mg/ml solution for injection for cattle
(AT, BE, BG, CZ, DE, EE, EL, ES,FI, IT, LT, LV, NL, PL, PT, RO, SI, SK)

Ancesol solution for injection for cattle
(FR)

Chlorphenamine maleate

2. STATEMENT OF ACTIVE SUBSTANCES

Chlorphenamine maleate 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or slow intravenous administration.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 1 day
Milk: 12 hours

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

EXP {month/year}

Once broached, use within 28 days by ....

11. SPECIAL STORAGE CONDITIONS

After first opening do not store above 30 °C.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Richter Pharma AG, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

XXXX

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Ancesol 10 mg/ml solution for injection for cattle
(AT, BE, BG, CZ, DE, EE, EL, ES, FI, IT, LT, LV, NL, PL, PT, RO, SI, SK)

Ancesol solution for injection for cattle
(FR)

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

Marketing authorisation holder:
Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria

Manufacturer responsible for batch release:
Richter Pharma AG, Durisolstrasse 14, 4600 Wels, Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ancesol 10 mg/ml solution for injection for cattle
(AT, BE, BG, CZ, DE, EE, EL, ES, FI, IT, LT, LV, NL, PL, PT, RO, SI, SK)

Ancesol solution for injection for cattle
(FR)

Chlorphenamine maleate

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

Each ml contains:

Active substance:

Chlorphenamine maleate (equivalent to 7.03 mg chlorphenamine)	10 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.00 mg
Propyl parahydroxybenzoate	0.20 mg

Clear, colourless to almost colourless solution

4. INDICATION(S)

For the symptomatic treatment of conditions associated with histamine release.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Chlorphenamine has a weak sedative effect.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

For intramuscular or slow intravenous use, see also section "9. Advice on correct administration".

Adult animals:
0.5 mg Chlorphenamine maleate/kg bodyweight (5 ml/100 kg bodyweight), once a day for three consecutive days.

Calves:
1 mg Chlorphenamine maleate/kg bodyweight (10 ml/100 kg bodyweight), once a day for three consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

Although intravenous administration has an immediate therapeutic effect, it can have excitatory effects on the CNS. Consequently, administer slowly and interrupt administration for a few minutes if necessary, when using this route.
Do not administer via the subcutaneous route.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 1 day
Milk: 12 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days
After first opening do not store above 30 °C.

12. SPECIAL WARNING(S)

Special warnings for each target species
None

Pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only in accordance with the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
Concomitant use of other antihistamines or barbiturates may boost the sedative effect of chlorphenamine. The use of antihistamines may conceal early signs of ototoxicity caused by some antibiotics (e.g. aminoglycoside and macrolide antibiotics) and may shorten the effect of oral anticoagulants.

Overdose (symptoms, emergency procedures, antidotes)
Doses up to four times the therapeutic dose have been well tolerated. In very rare cases, local reactions were observed in the neck region at the injection site. All the reactions were transient and resolved spontaneously.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Accidental self-injection may result in sedation. Care should be taken to avoid accidental self-injection with this drug. Preferably use a guarded needle until the moment of injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE.
Wash splashes from skin and eyes immediately.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

XXXX

15. OTHER INFORMATION

Package sizes
1 x 100 ml, 5 x 100 ml
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.