

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 1 x 50 ml vial
1 x 100 ml vial
1 x 250 ml vial
10 x 100 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pronestestic 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (AT, BE, CY, CZ, DE, DK, EE, EL, ES, HR, IE, IT, LT, LU, LV, NL, PL, PT, SI, SK, UK)

Pronestestic vet 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (FI, IS, SE)

Malleva vet 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (NO)

Pronestestic 34.65 mg/ml / 0.02 mg/ml solution for injection for horses, cattle, pigs and sheep (FR)

procaine hydrochloride/epinephrine tartrate

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES (AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, HR, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, SE, SI, SK, UK)

1 ml:

Active substances: procaine hydrochloride 40 mg (equivalent to 34.65 mg procaine) - epinephrine tartrate 0.036 mg (equivalent to 0.02 mg epinephrine); **Excipients:** sodium metabisulfite (E223) - sodium methyl parahydroxybenzoate (E219) - disodium edetate.

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES (FR)

1 ml:

Active substances: procaine (as hydrochloride) 34.65 mg (equivalent to 40 mg procaine hydrochloride) - epinephrine (as tartrate) 0.02 mg (equivalent to 0.036 mg epinephrine tartrate); **Excipients:** sodium metabisulfite (E223) - sodium methyl parahydroxybenzoate (E219) - disodium edetate

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml
10 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous and perineural use
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: zero days.
Milk: zero hours.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month /year}
Shelf-life after first opening the vial: 28 days
Once opened, use by _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.

12. SPECIFIC 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

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

FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (Bologna), Italy.

16. MARKETING AUTHORISATION NUMBERS

[To be completed nationally]

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pronestestic 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (AT, BE, CY, CZ, DE, DK, EE, EL, ES, HR, IE, IT, LT, LU, LV, NL, PL, PT, SI, SK, UK)

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Malleva vet 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (NO)

Pronestestic 34.65 mg/ml / 0.02 mg/ml solution for injection for horses, cattle, pigs and sheep (FR)

procaine hydrochloride/epinephrine tartrate

2. QUANTITY OF ACTIVE SUBSTANCES (AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, HR, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, SE, SI, SK, UK)

1 ml: procaine hydrochloride 40 mg (equivalent to 34.65 mg procaine) - epinephrine tartrate 0.036 mg (equivalent to 0.02 mg epinephrine).

2. QUANTITY OF ACTIVE SUBSTANCES (FR)

1 ml: procaine (as hydrochloride) 34.65 mg (equivalent to 40 mg procaine hydrochloride) - epinephrine (as tartrate) 0.02 mg (equivalent to 0.036 mg epinephrine tartrate).

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

50 ml

4. ROUTE(S) ADMINISTRATION

SC, perineural use

5. WITHDRAWAL PERIOD

Withdrawal period:

Meat and offal: zero days.

Milk: zero hours.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month /year}

Shelf-life after first opening the vial: 28 days.

Once broached, use by _____

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml label

250 ml label

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procaine hydrochloride/epinephrine tartrate

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3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Horses, cattle, pigs and sheep

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

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8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: zero days.
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