

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 vial of 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEDAQUICK 10 mg/ml solution for injection for horses and cattle (ES, IT, PT)
Detomidine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Detomidine 8.36 mg
(equivalent to detomidine hydrochloride 10.0 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Horses and cattle

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous and intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Horses and cattle
Meat and offal: 2 days
Milk: 12 hours

9. SPECIAL WARNING(S), IF NECESSARY

Alpha 2-adrenoreceptor agonists can cause severe adverse reactions.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month /year}

Once broached use within 28 days

Once broached use by

11. SPECIAL STORAGE CONDITIONS

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.

To be supplied only on veterinary prescription.

(For Spain only, include: administration only by a veterinary surgeon.)

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

40064, Ozzano dell’Emilia (BO)

Italy

Distributed by:

To be completed nationally

16. MARKETING AUTHORISATION NUMBER

To be completed nationally.

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEDAQUICK 10 mg/ml solution for injection for horses and cattle (ES, IT, PT)
Detomidine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains: Detomidine 8.36 mg (equivalent to detomidine hydrochloride 10.0 mg).

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

10 ml

4. ROUTES OF ADMINISTRATION

Intravenous and intramuscular use.

5. WITHDRAWAL PERIOD(S)

Horses and cattle
Meat and offal: 2 days
Milk: 12 hours

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.