ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

for 10 ml / 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sensiblex 40 mg/ml solution for injection for cattle
Denaverine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Denaverine hydrochloride 40 mg/ml (equivalent to 36.5 mg/ml Denaverine)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml
50 ml

5. TARGET SPECIES

Cattle (cows, heifers)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 1 day
Milk: 24 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use. The product has a potential to affect uterine musculature. Therefore, pregnant women and those women who are attempting to conceive should not handle or administer the product.

10. EXPIRY DATE

Expiry date: month/year
Shelf life after first broaching the vial: 28 days

11. SPECIAL STORAGE CONDITIONS

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

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 27569/4006

17. MANUFACTURER'S BATCH NUMBER

Batch number:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml / 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sensiblex 40 mg/ml solution for injection for cattle
Denaverine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

40 mg/ml

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

10 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 1 day
Milk: 24 hours

6. BATCH NUMBER

Batch number:

7. EXPIRY DATE

Expiry date: month/year
Once broached use by:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Sensiblex 40 mg/ml solution for injection for cattle

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

Marketing authorisation holder and manufacturer responsible for batch release:
Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sensiblex 40 mg/ml solution for injection for cattle
Denaverine hydrochloride

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

Sensiblex is a clear colourless solution for injection containing:
Active substance:
Denaverine hydrochloride 40.0 mg/ml (equivalent to 36.5 mg/ml Denaverine)
Excipients:
Benzyl alcohol (E1519) 20.0 mg/ml

4. INDICATION(S)

Cows, heifers:
- Promotes dilation of the soft tissues of the birth canal in cases where the birth canal is insufficiently opened.
- Regulates uterine contractions during parturition in animals with hypertonic muscular contractions of the uterus.

Heifers:
- Promotes dilation of the soft tissues of the birth canal to facilitate parturition.

5. CONTRAINDICATIONS

Do not administer in cases of mechanical obstetrical obstructions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Increased restlessness; swellings at the injection site; absent or insufficient effectiveness necessitating further obstetric diagnostics and measures.

If you notice any side effects, even those not already listed in this package leaflet or if you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (cows, heifers)

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

For intramuscular use.

Heifers: 10.0 ml product (400 mg Denaverine hydrochloride / animal)
Cows: 10.0 ml product (400 mg Denaverine hydrochloride / animal)

9. ADVICE ON CORRECT ADMINISTRATION

Timing of product administration:

- Use in heifers to facilitate parturition: the product should be administered as soon as parts of the foetus are within the cervical canal and abdominal pressing has already started.

- Use in heifers and cows to promote dilation of the soft tissues of the birth canal: the product can be administered immediately after the veterinary surgeon has determined that insufficient opening of the soft birth canal is present (please also refer to section 5 [contraindications] and 12 [special warnings] of the Package Leaflet).

In cases where full dilation is not achieved, product administration may be repeated once after 40 – 60 minutes.

10. WITHDRAWAL PERIOD

Meat and offal: 1 day
Milk: 24 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after “EXP”. The expiry date refers to the last day of that month. Shelf life after first opening the immediate packaging: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:

The product is ineffective if no part of the foetus has already entered the cervical canal and if abdominal pressing has not started.
Before administering the product it is important to ensure there are no mechanical obstructions (e.g. oversized foetus, malpresentation, uterine torsion). If present, obstructions must be removed prior to product administration (e.g. correction of abnormal presentation or uterine torsion).
Signs of peripartum electrolyte imbalances (with special attention to calcium and phosphorus), as well as metabolic disturbances (e.g. ketosis), both possibly causing weak labour and thus insufficient dilation of the soft birth canal, require particular consideration and supportive measurements.

Special precautions for use in animals:

None.

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

The product has a potential to affect uterine musculature. Therefore, pregnant women and those women who are attempting to conceive should not handle or administer the product. Administration should be performed with caution in order to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Accidental spillage onto skin or into the eyes should be thoroughly rinsed off with water.
People with known hypersensitivity to denaverine hydrochloride or to any of the excipients should not administer the product.
Wash hands after use.

Pregnancy:
Use at the time of parturition only. Not for use during other stages of pregnancy or during lactation.

Interaction with other medicinal products and other forms of interaction:
The product should not be mixed with other veterinary medicinal products. In the case of additional administration of oxytocin or its analogues, the dose of this active substance must be carefully selected because denaverine may amplify its effects.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdose or intravenous application, anticholinergic effects, e.g. increased heart and decreased respiration rate may occur.

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

1 vial (10 ml) in a cardboard box
1 vial (50 ml) in a cardboard box

Not all pack sizes may be marketed.

Approved 27 July 2022