

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sensiblex 40 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Denaverine hydrochloride 40.0 mg
(equivalent to 36.5 mg Denaverine)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519)	20.0 mg
Propylene glycol	
Hydrochloric acid (for pH adjustment)	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows, heifers)

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in cases of mechanical obstetrical obstructions.

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

3.4 Special warnings

The veterinary medicinal product is ineffective if no part of the foetus has already entered the cervical canal and if abdominal pressing has not started.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

The veterinary medicinal 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 veterinary medicinal 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 avoid contact with the veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (cows, heifers):

Undetermined frequency (cannot be estimated from the available data)	Injection site swelling Restlessness ¹ Lack of efficacy ²
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¹ Increased

² Or insufficient effectiveness, necessitating further obstetric diagnostics and measures

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Use only at the time of parturition. Do not use during other stages of pregnancy or during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal 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.

3.9 Administration routes and dosage

Intramuscular use.

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

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

Timing of veterinary medicinal product administration:

- Use in heifers to facilitate parturition: the veterinary medicinal 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 veterinary medicinal 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 3.3 “Contraindications” and 3.4 “Special warnings”).

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose or intravenous application, anticholinergic effects, e.g. increased heart and decreased respiration rate may occur.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle:

Meat and offal: 1 day

Milk: 24 hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG02CX90

4.2 Pharmacodynamics

Denaverine hydrochloride is a spasmolytic agent with a relaxant effect on smooth muscle. It has a relaxing effect on the uterus *sub partu* and increases the distensibility of the soft-tissue of the birth canal. Following intramuscular injection the spasmolytic effect commences within 15 to 30 minutes and lasts for several hours. The mechanism of action is not known.

4.3 Pharmacokinetics

Denaverine is excreted rapidly from the treated animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Vial of colourless glass, type I, with a fluorinated bromobutyl rubber stopper and an aluminium cap.

Pack sizes:

1 vial (10 ml) in a cardboard box.

1 vial (50 ml) in a cardboard box.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 27569/4006

8. DATE OF FIRST AUTHORISATION

15 June 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 21 July 2026