

Sensiblex[®]



Denaverine hydrochloride
40 mg/ml

- Tocospasmolytic
- Eased parturition due to improved dilation of the soft tissues of the birth canal
- Lower frequency of retained placenta and lower rate of birth injuries in the dam
- Minimised neonatal mortality





Sensiblex® is the only veterinary product throughout Europe authorised for the therapy to facilitate parturition in cattle. The benefit of the preparation in terms of animal welfare is confirmed by numerous clinical studies. When administered sub partu, Sensiblex® promotes elasticity of the soft birth canal and regulates labour in case of too strong uterine contractions. Due to the rapid onset of effect parturition is facilitated.

Sensiblex® 40 mg/ml 40 mg/ml solution for injection for cattle

Statement of active substance(s) and other ingredient(s)

Each ml contains:

Active substance:

Denaverine hydrochloride 40.0 mg (equivalent to 36.5 mg Denaverine)

Excipients:

Benzyl alcohol (E1519) 20.0 mg

Indications

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.

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.

Adverse reactions

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

Target species

Cattle (cows, heifers)

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)

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 "contraindications" and "special warnings" of the Package Leaflet).

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

Withdrawal period

Meat and offal: 1 day

Milk: 24 hours

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 breached (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.

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), if necessary

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.

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.

Available only on prescription

Package sizes

10 ml vial

50 ml bottle

The information given in this product brochure conforms to the state of knowledge upon completion. Please read the package leaflet before using the veterinary medicinal product. You will find more details on Sensiblex® in our Fact Sheet which also comprises studies and practical experiences with the product. Please feel free to contact us.

Our Fact Sheets are also provided on our website under

www.veyx.com/products/animal-holders

Veyx-Pharma is GMP-, QS- and VLOG-certified.

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