Sensiblex®

www.veyx.com

40 mg/ml solution for injection for cattle

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT
Sensiblex® 40 mg/ml solution for injection for cattle

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS
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 PERIODS
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 broached (opened) for the first time, using the in-use shelflife 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

OTHER INFORMATION
Package sizes:
10 ml vial
50 ml bottle

Not all package sizes may be marketed.