

# Sensiblex®



## Solution for injection in 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  
Denaverine hydrochloride

### STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

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

### 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 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 disorders.

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 obstetrical measures.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon or pharmacist.

### TARGET SPECIES

Cattle (cows, heifers)

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

For intramuscular use.

*Heifers:* 10.0 ml Sensiblex® (400 mg Denaverine hydrochloride/animal)

*Cows:* 10.0 ml Sensiblex® (400 mg Denaverine hydrochloride/animal)

### 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 have entered the cervical canal and abdominal pressing has started.

- Use in heifers and cows to enhance 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 kindly also refer to section Contraindications and Special warnings).

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

### **WITHDRAWAL PERIODS**

Cattle: Meat and offal:	1 day
Milk:	24 hours

### **SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight 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.

### **SPECIAL WARNING(S)**

#### Special warnings for each target species:

The product is ineffective if no part of the foetus has 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). If present, obstructions must be removed prior to product administration (e.g. correction of abnormal presentation or uterine torsion).

#### 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:

Sensiblex<sup>®</sup> 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. Do not exceed the recommended dose.

#### 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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Available only on prescription

### **OTHER INFORMATION**

Package sizes:

10 ml vial  
50 ml bottle

Not all package sizes may be marketed.