# 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

1 ml contains:

**Active substance:**
Denaverine hydrochloride 40.0 mg (equivalent to 36.5 mg Denaverine)

**Excipients:**
Benzyl alcohol (E1519) 20.0 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle (cows, heifers)

### 4.2 Indications for use, specifying the 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 in animals with hypertonic muscular contractions of the uterus.

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

### 4.3 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.

## 4.4 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).

## 4.5 Special precautions for use

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.

## 4.6 Adverse reactions (frequency and seriousness)

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

## 4.7 Use during pregnancy, lactation or lay

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

## 4.8 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.

## 4.9 Amounts to be administered and administration route

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 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 4.3 [contraindications] and 4.4 [special warnings] of the SPC).

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

### 4.10 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.

### 4.11 Withdrawal period(s)

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

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Genitourinary system and sex hormones; other gynaecologicals

ATCvet code: QG02CX90

### 5.1 Pharmacodynamic properties

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.

### 5.2 Pharmacokinetic particulars

Denaverine is excreted rapidly from the treated animals.

## 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Benzyl alcohol (E1519)
Propylene glycol
Hydrochloric acid (for pH adjustment)
Water for injections

## 6.2 Incompatibilities

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

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
2 years
Shelf life after first opening the immediate packaging:
28 days

## 6.4 Special precautions for storage

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

## 6.5 Nature and composition of immediate packaging

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

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

Not all pack sizes may be marketed.

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

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

# 7. MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

# 8. MARKETING AUTHORISATION NUMBER

Vm 27569/4006

## 9. DATE OF FIRST AUTHORISATION

15 June 2017

## 10. DATE OF REVISION OF THE TEXT

June 2017

**Approved: 15/06/2017**