Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Planipart Solution for Injection 30 microgram/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Clenbuterol hydrochloride 30 micrograms

Excipients:
Benzyl alcohol 10 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Pale yellow, clear solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

To relax the uterus in cattle, usually at the time of parturition. In particular:

1. In heifers to delay delivery to allow full preparation of the soft birth canal.
2. As an aid to obstetrical manoeuvres in dystocia, e.g. malpresentation and malposture.
3. To relax the uterus for Caesarean section.
4. To delay and therefore programme delivery to permit observation of parturition, e.g. avoidance of night time delivery.
5. To facilitate the replacement of prolapsed uterus.
6. In embryo transfer technique to ensure less traumatic manipulation of the uterus.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

The earlier in the stage of labour that treatment is given, the longer will be the period of abolition of uterine contraction. Once the cervix is fully dilated or the foetal feet are passing into the cervical area, the product will only delay parturition for a maximum of a few hours.

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

When using do not eat, drink or smoke. After use, wash any contaminated skin immediately with soap and clean water. This product contains clenbuterol, a beta-agonist. Accidental self-injection may cause tachycardia and tremor. These effects may be reversed by the use of a non-selective beta-blocker. It accidental self-injection occurs seek medical advice immediately, avoiding driving if possible.

Clenbuterol decreases the tonus of the uterine muscles. Pregnant women should avoid any risk of exposure to Planipart and should not administer the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

This product is indicated for use during the early (embryo transfer) or the final stages of pregnancy as well as during labour. Use of the product has not been shown to adversely affect the viability of the new-born animal nor the normal course of the post-partum period including subsequent fertility. In case of lactation the withdrawal time for milk has to be considered.

4.8 Interaction with other medicinal products and other forms of interactions

Not to be used in conjunction with atropine.
Not to be used with general anaesthesia because of a possible hypotensive effect.
Antagonistic to the effects of prostaglandin F2-alpha and oxytocin.
The product is a beta-adrenergic stimulant and is therefore antagonised by beta-adrenergic blocking agents.
In order to prevent additive effects, the product should not be given with other sympathomimetics or vasodilators.

4.9 Amounts to be administered and administration route

10 ml by slow intravenous route as a single injection.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of accidental overdosage a ß-blocker, such as propranolol, may be used as antidote.

4.11 Withdrawal period(s)

Meat and offal: 14 days.
Milk: 60 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sympathomimetics, labour repressants.
ATCvet code: QG02CA91

5.1 Pharmacodynamic properties

Clenbuterol is a beta-sympathomimetic agonist which has potent bronchodilator and tocolytic properties. The earlier in the stage of labour that treatment is given, the longer will be the period of abolition of uterine contractions. Once the cervix is fully dilated or the foetal feet are passing into the cervical area, Planipart will only delay parturition for a maximum of a few hours.

5.2 Pharmacokinetic particulars

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Benzyl Alcohol
Hydrochloric Acid
Water for Injection

6.2 Major incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

50 ml amber glass injection vial (Ph. Eur. Type II) with pink brombutyl rubber stopper and aluminium crimp cap.

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

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

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

November 2018