SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planipart Solution for Injection 30 micrograms/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, please see 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Pale yellow, clear solution for injection, pH 7.0.

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 Caesarian 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 to ensure less traumatic manipulation of the uterus.

4.3 Contraindications

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

4.4 Special warnings

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

i. Special Precautions for use in the animals

None

ii. Special precautions to be taken by the person administering the veterinary medicinal product to the animal

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. If 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

None known

4.7 Use during Pregnancy and Lactation

This product is indicated for use during the early (embryo transfer) or the final stages of pregnancy as well as during labour. The 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 Medicaments and other forms of nteraction

Not to be used in conjunction with atropine.
Not to be used with general aneasthesia because of the possible hypotensive effects.
Antagonistic to the effects of prostaglandin F2α and oxytocin.
The product is a β-adrenergic stimulant and is therefore antagonised by β-blocking agents. In order to prevent additive effects, the product should not be given with other sympathomimetics or vasodilators.

4.9 Amount to be administered and administration route

10 ml by slow intravenous as a single injection.

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

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

4.11 Withdrawal Periods

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

5. PHARMACOLOGICAL PROPERTIES

ATCVet code : QG02CA91 Sympathomimetics, labour repressants.

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, The product will only delay parturition for a maximum of a few hours.

5.2 Pharmacokinetic properties

Clenbuterol and its metabolites are rapidly distributed and excreted. Most of the dose is excreted by 96 hours, largely as clenbuterol.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Sodium chloride
Hydrochloric acid
Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the medicinal product as packaged for sale : 3 years
Shelf life after first broaching the immediate packaging : 28 days.

6.4 Special Precautions for Storage

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

6.5 Nature and composition of immediate packaging

50 ml amber glass injection vial (Ph Eur. Type II) with pink bromobutyl 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, if appropriate.

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 Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4299

9. DATE OF FIRST AUTHORISATION

01 August 1994

10. DATE OF REVISION OF THE TEXT

December 2018

Approved 06 December 2018