PARTICULARS TO APPEAR ON THE OUTER PACKAGE
1 x 50 ml carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planipart Solution for Injection 30 micrograms/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 30 micrograms clenbuterol hydrochloride and 10 mg benzyl alcohol (preservative).

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By slow i.v. injection. 10 ml per animal as a single injection.

8. WITHDRAWAL PERIOD

Milk: 60 hours

Meat: 14 days

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals with known hypersensitivity to the active ingredient.
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 F_2 alpha and oxytocin. Planipart is a beta-adrenergic stimulant and is therefore antagonised by betaadrenergic blocking agents. In order to prevent additive effects, the product should not be given with other sympathomimetics or vasodilators.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Do not store above 25° C. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For further information on uses, disposal advice, dosage, user safety and warnings, please refer to the enclosed package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

UK	POM-V
IE	VPO

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4299

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
1 x 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planipart Solution for Injection 30 micrograms/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 30 micrograms clenbuterol hydrochloride and 10 mg benzyl alcohol (preservative).

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By slow i.v. injection. 10 ml per animal as a single injection.

8. WITHDRAWAL PERIOD

Milk: 60 hours. Meat: 14 days

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals with a known hypersensitivity to the active ingredient. 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 F_2-alpha and oxytocin. Planipart is a betaadrenergic 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.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For further information on uses, dosage, disposal advice, user safety and warnings, please refer to the enclosed package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

UK	POM-V
IE	VPO

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer
Labiana Life Sciences, S.A. 08228
Terassa, Barcelona, Spain.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4299

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer:
Labiana Life Sciences, S.A. 08228
Terassa, Barcelona, Spain.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Planipart Solution for Injection 30 micrograms/ml

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Sterile solution for injection.

Each ml contains 30 micrograms clenbuterol hydrochloride and 10 mg benzyl alcohol (preservative).

4. INDICATION(S)

Planipart is indicated to relax the uterus in cattle, usually at the time of parturition.

In particular:

- To relax the uterus for Caesarean section.
- As an aid to obstetrical manoeuvres in dystocia eg. Malpresentation and malposture.
- To delay delivery to allow full cervical dilation, i.e. preparation of the soft birth canal.
- To facilitate the replacement of prolapsed uterus.
- In embryo transfer to ensure less traumatic manipulation of the uterus.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient. 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 F_2-alpha and oxytocin. Planipart 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. In case of accidental overdose, a betablocker, such as propranolol, may be used as antidote.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cattle

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

10 ml by slow intravenous route as a single injection. The earlier in the stage of labour that treatment is given, the longer will be the period of delay of parturition. 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. The use of Planipart has not been shown to adversely affect the viability of the newborn animal.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken during treatment or within 60 hours of the last treatment. Animals must not be slaughtered for human consumption during treatment or within 14 days of the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Protect from light. Do not store above 25°C. Do not use after the stated expiry date. Following withdrawal of the first dose, use the product within 28 days. Should any apparent growth or discolouration occur, the product should be discarded. When the container is broached for the first time, using the in-use shelf life which is specified in this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. The discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S)

User safety warnings : 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 produce tachycardia and tremor. These effects may be reversed by the use of a non-selective beta-blocker. Clenbuterol decreases the tonus of the uterine muscles. Pregnant women should avoid any risk of exposure to Planipart and should not administer the product. If accidental self-injection occurs seek medical advice immediately, avoiding driving if possible.

For animal treatment only

Keep out of sight and reach of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2020

15. OTHER INFORMATION

UK	POM-V
IE	VPO

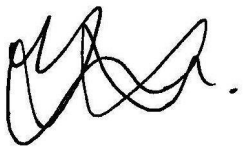
UK: To be supplied only on veterinary prescription.

IE: Veterinary Practitioner Only

Marketing Authorisation numbers:

Vm 08327/4299

Package Quantities: Amber vials containing 50 ml of solution.



Approved: 18 February 2020