ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing a vial of 20 ml or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix solution for injection (250 microgram/ml) for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Cloprostenol sodium 263 µg/ml
(corresponding to 250 µg/ml cloprostenol)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml

5. TARGET SPECIES

Cows

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal:	2 days
Milk:	0 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP :{month/year}

Once opened, use by 28 days.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.
Protect from light.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

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

Virbac
1ère avenue – 2065 m – L.I.D
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4157

17. MANUFACTURER'S BATCH NUMBER

Batch : {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 20 ml or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix solution for injection (250 microgram/ml) for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cloprostenol sodium 263 µg/ml
(corresponding to 250 µg/ml cloprostenol)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM use.

5. WITHDRAWAL PERIOD

Meat and offal: 2 days
Milk: 0 days

6. BATCH NUMBER

Batch :{number}

7. EXPIRY DATE

EXP :{month/year}
Once opened, use by 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
To be supplied only on veterinary prescription

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Cyclix solution for injection (250 microgram/ml) for cattle

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

Marketing authorisation holder and manufacturer responsible for batch release:
Virbac
1ère avenue – 2065 m – L.I.D
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclix solution for injection (250 microgram/ml) for cattle
Spain: Cyclix bovino 250 µg/ml solucion inyectable
Sweden: Cyclix 250 mikrogram/ml injektionsvätska, lösning för nötkreatur
UK/Ireland: Cyclix 250 microgram/ml solution for injection for cattle
Austria: Cyclix 250 µg/ml – Injektionslösung für Kühe
Italy: Cyclix bovini 250 µg/ml soluzione iniettabile

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

1 ml solution for injection contains:

Active substance(s):
Cloprostenol sodium 263 micrograms
(corresponding to 250 micrograms cloprostenol)

Excipients:
Benzyl alcohol (E1519) 20 mg

Colourless solution.

4. INDICATION(S)

Induction of luteolysis allowing resumption of oestrus and ovulation in cyclic females when used during dioestrus, synchronisation of oestrus (within 2 to 5 days) in groups of cyclic females treated simultaneously, treatment of suboestrus and uterine disorders related to a functioning or persistent corpus luteum (endometritis, pyometra), treatment of ovarian luteal cysts, induction of abortion until day 150 of pregnancy, expulsion of mummified foetuses, induction of parturition.

5. CONTRAINDICATIONS

Do not use in pregnant animals, for which induction of abortion or parturition is not intended.

Do not use in animals with spastic diseases of the respiratory or gastrointestinal tract.

6. ADVERSE REACTIONS

Anaerobic infection may occur if anaerobic bacteria penetrate the tissue at injection site, in particular following intramuscular injection.
When used for induction of parturition and dependent on the time of treatment relative to the date of conception, the incidence of retained placenta may be increased.
In very rare cases, anaphylactic-type reactions can be observed which might be life-threatening and require rapid medical care.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Cows.

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

For all indications, 2 ml corresponding to 0,5 mg cloprostenol/animal, injected intramuscularly.

9. ADVICE ON CORRECT ADMINISTRATION

In order to synchronise oestrus in groups of females, it is recommended that the product is administered on two occasions with a between treatment interval of 11 days.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 2 days
Milk: 0 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the vial in the outer carton.
Protect from light.

Do not use after the expiry date stated on the outer carton.
After first opening the product may be stored for 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals
As with parenteral administration of any substance, basic aseptic rules should be observed. The injection site must be thoroughly cleaned and disinfected in order to reduce the risk of infection with anaerobic bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to benzyl alcohol should avoid contact with the product. Do not eat, drink or smoke while handling the product. Direct contact with skin or mucous membranes of the user should be avoided. Prostaglandins of the $F_{2\alpha}$ type may be absorbed through the skin and may cause bronchospasm or miscarriage. The product must be handled carefully to avoid ACCIDENTAL SELF-INJECTION OR SKIN CONTACT. Pregnant women, women in childbearing age, asthmatics and persons with other respiratory tract diseases should exercise caution when handling cloprostenol. Those persons should wear rubber (or plastic) gloves during administration of the product. Accidental spillage on the skin should be washed immediately with soap and water.
In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

Pregnancy and lactation
Do not use in pregnant animals, for which abortion or induction of parturition is not intended. The product can be safely used during lactation.

Interaction with other medicinal products and other forms of interaction
Concurrent use of oxytocin and cloprostenol increases effects on the uterus. The activity of other oxytocic agents can be increased after the administration of cloprostenol.
Do not use in animals being treated with non-steroidal anti-inflammatories, as the synthesis of endogenous prostaglandins is inhibited.

Overdose (symptoms, emergency procedures, antidotes)
Therapeutic tolerance in cattle is broad. Overdoses of more than 10 times are generally well tolerated. Large overdoses may cause transient diarrhoea. No antidotes are available.
An overdose will not accelerate corpus luteum regression.

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

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

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Approved 29 June 2020