ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovuplant 2.1 mg
Implantation tablets
For horses (mares)
Deslorelin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 implant contains:
Active substance:
Deslorelin (as deslorelin acetate) 2.1 mg

3. PHARMACEUTICAL FORM

Implantation tablets

4. PACKAGE SIZE

Five implants preloaded in syringes (implanters).

5. TARGET SPECIES

Horses (non-pregnant mares).

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.
One implant should be placed subcutaneously in the neck of a mare when a developing follicle greater than 30 mm in diameter is present. Only one (1) implant should be administered per mare during a given oestrus. The biocompatible implant is absorbed and does not require removal.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal:7 days.
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Please read the package leaflet for user warnings.
Read the package leaflet before use.
Do not use if foil pouch is broken.
For subcutaneous use only in mares.
Do not attempt to re-use the implanter.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C to 8°C).

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

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

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.

UK:

POM-

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

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBERS

Vm 10434/4063

17. MANUFACTURER'S BATCH NUMBER

Lot:

18. OTHER INFORMATION

Developed and manufactured by:
Peptech Animal Health Pty
19-25 Khartoum Road
Macquarie Park,
NSW 2113
Australia

UK: Local representative: Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS,United Kingdom

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FOIL POUCH

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovuplant 2.1 mg
Implantation tablets
For horses (mares)
Deslorelin

2. QUANTITY OF THE ACTIVE SUBSTANCE

1 implant contains:
Active substance:
Deslorelin (as deslorelin acetate) 2.1 mg

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

One implant preloaded in one syringe (implanter)

4. ROUTE OF ADMINISTRATION

Subcutaneous use.
Place one implant subcutaneously in the neck of a mare when a developing follicle greater than 30 mm in diameter is present. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment. Only one implant should be administered per mare during a given oestrus.

5. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 7 days.
Do not use in mares producing milk for human consumption.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

UK: Vm 10434/4063

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B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Ovuplant 2.1 mg
Implantation tablets for horses (mares)

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

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturer responsible for batch release:
Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovuplant 2.1 mg implantation tablets for horses (mares)
Deslorelin

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

1 implant contains:
Active substance:
Deslorelin (as deslorelin acetate) 2.1 mg

4. INDICATION(S)

In mares - zootechnical treatment for the induction of ovulation within 48 hours, during oestrus in normally cycling mares (in sexual season), with an ovarian follicle greater than 30 mm diameter.

5. CONTRAINDICATIONS

Do not use in horses producing milk for human consumption.
Do not use during pregnancy. GnRH analogues have been shown to be foetotoxic in laboratory animals when administered during pregnancy.

6. ADVERSE REACTIONS

Localised swelling and mild fibrosis at the site of implantation has been observed in some mares, accompanied by a slight increase in sensitivity to touch and an elevated skin temperature. These effects are transient and usually resolve without treatment within 2 to 5 days.
Some mares implanted with the veterinary medicinal product (deslorelin) may experience an increased dioestrus period following use.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses (non-pregnant mares).

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

Place one implant subcutaneously in the neck of a mare that has been determined by rectal palpation and/or ultrasonography to have an ovarian follicle greater than 30 mm in diameter.
Select the implant site by locating an area of the neck midway between the head and shoulder. Prepare the implantation site by thoroughly cleaning the skin with an appropriate disinfectant. Insert the entire length of the needle subcutaneously and fully depress the syringe plunger. Slowly withdraw the needle while pressing the skin at the insertion site. Examine the syringe and needle to ascertain that the implant has not remained within the syringe or needle. It may be possible to palpate the implant *in situ*.
Do not attempt to re-use the implanter.
The biocompatible implant is absorbed and does not require removal.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Meat and offal:7 days.
Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C-8°C).

12. SPECIAL WARNING(S)

Special warnings for each target species:
Mares should be implanted with the veterinary medicinal product when a developing ovarian follicle greater than 30 mm in diameter has been detected by rectal palpation and/or ultrasonography. In larger breeds, it may be necessary to wait until the dominant follicle has progressed to 35 mm in diameter before administration of the veterinary medicinal product.
Treated mares should be bred or inseminated within the next 48 hours. The mare should be monitored to ensure that ovulation has occurred and that further breedings are not required. If ovulation does not occur within 48 hours of implantation, continue breeding according to routine management procedures.
It has been noted that follicles were significantly smaller before ovulation for deslorelin treated mares compared with placebo mares. However, treatment had no effect on the percentage of mares pregnant at days 18 or 50.
For all trials that evaluated conception and pregnancy rate, there were no differences between deslorelin-treated and non-treated mares at the end of the study.
Efficacy has not been established for mares in vernal (spring) transition phase.

Special precautions for use in animals:
Do not use if the foil pouch is broken.
Only one implant should be implanted per mare during a given oestrus.
The veterinary medicinal product has not been tested in mares less than three (3) years of age.
Use only in mares fit for reproduction.

User warnings:
Pregnant women should not administer the veterinary medicinal product as GnRH analogues have been shown to be foetotoxic in laboratory animals.
When administering the veterinary medicinal product, take care to avoid accidental
self-injection by ensuring that animals are suitably restrained and the application needle is shielded until the moment of implantation.
In the case of accidental self-injection, seek medical assistance immediately, with a view to having the implant removed, as GnRH analogues may have adverse effects on the male and female reproductive systems.
Although skin contact with the veterinary medicinal product is unlikely, should this occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin.

Use during pregnancy orlactation:
There is no requirement for use of the veterinary medicinal product during pregnancy. Do not use during pregnancy. GnRH analogues have been shown to be foetotoxic in laboratory animals when administered during pregnancy.

Overdose (symptoms, emergency procedures, antidotes):
In safety and tolerance studies, the only systemic adverse effect seen in mares receiving up to 10 implants simultaneously was suppression of ovarian activity.

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

03/2019

15. OTHER INFORMATION

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

UK: Vm 10434/4063

POM-V

Prescription Only Medicine – Veterinarian

Package quantities: 5 preloaded syringes (implanters) per carton.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:
UK: Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom

Approved: 23 May 2019