PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

25 sponges

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:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

2. Name of the veterinary medicinal product

OVIGEST 60 mg medicated sponge for ewes
Medroxyprogesterone

3. Statement of the active substance(s) and other ingredients

Composition per sponge:

Active substance:
Medroxyprogesterone acetate …….. 60 mg

Excipient(s):
Methylparahydroxybenzoate (E-218) …….. 3.6 mg
Propylparahydroxybenzoate (E-216) ……... 2 mg

4. Pharmaceutical form

Medicated sponge.

5. Package size

25 sponges.

6. Indication(s)

Ewes: Induction and synchronisation of oestrus during breeding and non-breeding season. During anoestrus periods OVIGEST should be used in conjunction with PMSG (Pregnant Mare Serum Gonadotrophin) to enhance ovulation.

7. Contraindications

Do not use in case of hypersensitivity to medroxyprogesterone.
Do not use in pregnant ewes
Do not use in unfertile and/or sexually immature ewes.
Do not use in ewes displaying vaginal flow, which have recently aborted, or which are ill.

8. Adverse reactions

Very rarely vaginitis, increase of vaginal flow and/or adherences between the mucosa and the sponge mayappear.

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).

9. Target species

Ewes.

10. Dosage for each species, route(s) and method of administration

Vaginal use.

Ewes: 1 sponge/animal.

11. Advice on correct administration

Clean the vulva of each ewe. Carefully, insert one sponge per ewe into the vagina with the aid of an applicator, which has been previously disinfected.

Remove the applicator leaving the retrieval strings hanging out of the vaginal opening.

The applicator should be cleaned after each insertion.

The sponge must remain inside the vagina for 12-14 days.

After the administration period, the sponge should be removed by gently pulling on the retrieval strings.

At removal of the sponge, a 500 IU PMSG injection can be administered to enhance ovulation, especially during the anoestrus period. In case of PMSG injection, it must not be administered before removing the sponge or from 6 h on after it has been removed (it may cause a diminution of the ovulation).

Ewes can be mated between 24-72 h after sponge removal. In case of artificial insemination it should be conducted 56 h after sponge withdrawal. Those ewes that have not been succesfully mated during first oestrus will come on heat again 15-17 days later. This second oestrus might also be used for mating.

12. Withdrawal period(s)

Meat and offal: 2 days.
Milk: 24 hours.

13. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 ºC.
Keep the bag tightly closed in order to protect from light.
Do not use after the expiry date stated on the packaging.
Once opened, use by 6 months.

14. Special warning(s)

Special warnings for each target species:
Medroxyprogesterone does neither constitute a therapy nor a curative approach to sterility.

Special precautions for use in animals:
Animals must be sexually mature and in good healthy conditions. If primiparous animals are used, these should be 7 months old at least and weigh 70 % of the expected adult body weight.
The sponges must be placed into the vagina with the aid of an applicator, which has been previously disinfected (alcohol, cresols and phenols are not recommended as disinfectants).
When the application of the sponges is difficult (excessively resistant hymen, malformations…) it should not be attempted to introduce the applicator by force, but to make a massage or manual rupture of the hymen, if necessary.
The sponge should be removed before the end of the treatment in the following situations:

- If blood is observed in the applicator after insertion.
- If the string brakes.
- In case abnormal secretion or acute metritis is observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to medroxyprogesterone should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women.

Use during pregnancy, lactation or lay:
The veterinary medicinal product can be used in lactating ewes, although less efficacy is expected. A minimum interval of 60 days is recommended between labour and treatment with sponges during the breeding season and 75 days during the anoestrus period.
Do not use during pregnancy.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
The administration route makes overdosing very unlikely.
The presence of sponges for a long period of time may produce vaginal irritation and endometric alterations.

Incompatibilities:
None known.

15. Special precautions for the disposal of unused products or waste materials, if any

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

16. Date on which the package leaflet was last approved

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17. Other information

18. 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.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP: {month/year}

21. Marketing authorisation number(s)

22. Manufacturer’s batch number

Batch/Lot: {number}