The format of this leaflet was determined by the Ministry of Health and its content checked and approved in February 2017.

CONSUMER PACKAGE INSERT FOR A VETERINARY MEDICINAL PRODUCT

The medicine is dispensed with a veterinarian's prescription only
For animal use only

1. NAME OF THE MEDICINE:

Flugestone Acetate Intervet 20 mg Veterinary, vaginal sponge

2. COMPOSITION:

Each polyester polyurethane sponge contains

Active ingredient(s)

Flugestone acetate, 20 mg

A list of inactive ingredients is detailed in the section "Further Information".

3. WHAT IS THE MEDICINE INTENDED FOR:

In ewes and ewe lambs, in combination with PMSG (Pregnant Mare Serum Gonadotropin)

- Induction and synchronization of oestrus and ovulation (in ewes during seasonal anoestrus and ewe lambs)
- Synchronization of oestrus and ovulation (in cycling ewes during seasonal oestrus and ewe-lambs).

Therapeutic group: Progestagen

4. CONTRAINDICATIONS:

Do not use during pregnancy.

Do not use together with alcohols, cresols, phenols, "sheep dips" or similar disinfectants.

5. SIDE EFFECTS:

A muco-purulent discharge may occasionally be observed upon sponge removal. This discharge is not associated with clinical signs and does not affect fertility.

Side effects may be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. TARGET ANIMALS:

Sheep (ewes and ewe lambs)

7. ADMINISTRATION AND DOSAGE:

Intra-vaginal sponge.

The dose is one sponge per animal irrespective of body weight, breed, type (dairy or meat) and season.

8. ADMINISTRATION OF PRODUCT:

The sponge is inserted intra-vaginally using an applicator.

Leave the sponge in place for 14 days. At the end of the administration period, gently remove the sponge by pulling on the string.

To obtain optimal synchronization of ovulation, an intramuscular injection of PMSG (300-700 I.U.) at the time of sponge removal is recommended.

In case fixed time artificial insemination is implemented, it is recommended to do so 55 hours after sponge removal.

9. WITHDRAWAL PERIODS:

Slaughter: 2 days after sponge withdrawal.

Milk: 0 hours, including the treatment period.

10. PRECAUTIONS:

- Special precautions regarding use in the target animal
  - Repeated use of the product in combination with PMSG may trigger the appearance of PMSG antibodies in some ewes. This in turn may affect the time of ovulation and result in reduced fertility when the product is combined with artificial insemination undertaken 55 hours after removal of the sponge.
  - There is no information regarding repeated use of the product within one year.
  - The use of an applicator designed for ewes or ewe lambs is recommended to enable correct insertion of sponges and to avoid vaginal injuries.
- Special precautions regarding safety of use of the medicine in animals

  None.
- Special safety precautions to be taken by the person handling the product
  - Direct contact with the skin should be avoided. Personal protective clothing (single use gloves) should be worn when handling the product. If contact with the skin occurs, wash the affected area with soap and water. Wash hands after treatment and before meals.
  - Human exposure to this product can affect fertility.
  - Women who are pregnant, or may be pregnant, must not come in contact with this product.
- Pregnancy and lactation

Can be used during lactation.

Do not use during pregnancy.

- Interactions with other medicines, and other forms of interactions

Do not use together with alcohols, cresols, phenols, “sheep dips” or similar disinfectants.

- Overdose

A five-fold dosage of flugestone acetate (100 mg/sponge) did not result in side effects.

- Incompatibility

None known.

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package/bottle. The expiry date refers to the last day of that month.
- Storage conditions

  Store in a dry place at a temperature below 25°C.

  Store the product in the original package.

  After opening the package, any unused product should be discarded.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE PRODUCT/UNUSED PRODUCT AFTER USE:

Any unused veterinary medical product or waste materials derived from such veterinary medicinal product use should be disposed of as toxic waste; do not discard into the wastewater.

13. FURTHER INFORMATION:

- In addition to the active ingredient(s), the medicine also contains:

  Hydroxypropylcellulose (e.g. Klucel E, or equivalent)

  Polyethylene glycol 4000

  Purified water

  Polyester Polyurethane Sponge

  Multifilament polyamide string high resistance (1.17 g/Km)
- What the medicine looks like and the contents of the package:
- Package size:

  10 sponges.

  25 sponges.

  50 sponges.
- **License holder name and address:**

  Intervet Israel Ltd., Industrial Zone Neve-Ne'eman, Hod Hasharon 45240.
- **Manufacturer name and address:**

  Intervet Productions SA, Rue de Lyons, 27460 Igoville, France

- **This leaflet was checked and approved by the Ministry of Health in** February 2017**.**
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health**

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