MSD Animal Health

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A Subsidiary of Merck & Co., Inc.,
Whitehouse Station, NJ, USA

31.05.2022

רופא/ה נכבד/ה,

ברצוננו להודיעך על אימוץ עלון לרופא לתכשיר:

Flugestone Acetate Intervet 20 mg veterinary, Sponge

חומר פעיל: Flugestone Acetate 20 mg

להלן עלון לרופא :

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flugestone Acetate Intervet 20 mg Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each polyester polyurethane sponge contains

Active substance(s)
Flugestone acetate, 20 mg.

List of excipients
Excipients qsp 1 sponge.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Vaginal sponge.
White cylindrical polyester polyurethane foam equipped with string.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep (ewes and ewe-lambs).

4.2 Indications for use

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

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

4.3 Contraindications

Please refer to section 4.7 and section 4.8.

4.4 Special warnings

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

- The repeated treatment with the product combined 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 combined with fixed time artificial insemination at 55h following sponge removal.
- The repeated use of sponges within one year has not been studied.
- The use of a vaginal applicator designed for ewes or ewe lambs is recommended to correctly insert sponges and to avoid vaginal injuries.

(ii) Special precautions to be taken by the person administering the medicinal product to animals

- Direct contact with the skin should be avoided. Personal protective clothing (single use gloves) should be worn when handling the product. If accidental contact with the skin occurs, wash the affected zone with soap and water. Wash hands after treatment and before meals.
- Human exposure to this product can affect fertility.
- Women who are pregnant, or suspected to be pregnant, must not use the product.

4.6 Adverse reactions

A muco-purulent discharge may occasionally be observed at sponge removal. It is not associated with clinical signs and does not alter fertility.

Reporting suspected adverse reactions:

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Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il

4.7 Use during pregnancy and lactation

Can be used during lactation.
The use is not recommended during gestation.

4.8 Interaction with other medicinal products and other forms of interaction

The sponges should not be used in conjunction with alcohols, cresols, phenols, sheep dips or similar disinfectants.

4.9 Amounts to be administered and administration route

The dose is one sponge per animal irrespective of body weight, breed, type (dairy or meat) and season.
The sponge is inserted intra-vaginally using an applicator.
Duration of sponge residence is 14 days. At the end of the administration period, the sponge is gently removed by pulling on its string.
To obtain an optimal synchronization of ovulation, an intra-muscular injection of PMSG (range 300-700 IU) is recommended (i.m.) at the time of sponge removal.
In case fixed time artificial insemination is applied, it is recommended to perform it 55 h after sponge removal.

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)

A five time overdose of flugestone acetate (100 mg/sponge) did not result in observable side effects.

4.11 Withdrawal periods

Meat: 2 days after withdrawal of sponges.
Milk: zero hours, including the treatment time.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: progestagen
ATC vet code: QG03D

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5.1 Pharmacodynamic properties

Flugestone acetate is a synthetic analogue of progesterone. It is approximately 20 fold more potent than progesterone and displays progestational activity but no anti-progestational, anti-androgenic or androgenic properties together with a low glucocorticoid activity.
Owing to its binding to the progesterone receptors, flugestone acetate acts by negative feedback on the hypothalamo-pituitary axis, suppressing pituitary release of gonadotrophins and therefore terminal follicular growth and ovulation.

5.2 Pharmacokinetic properties

Flugestone acetate is readily absorbed during the 12-14 days period of intravaginal administration. T_{max} ranges between 8 and 24 h, whereas C_{max} varies between 1.4 and 3.7 ng/ml. Steady state is reached quickly following onset of the treatment. Plasma cronolone concentrations are relatively constant throughout treatment. One day after removal of the Flugestone Acetate Intervet 20 mg Veterinary, flugestone acetate concentrations have dropped below the limit of quantification (LOQ = 0.04 ng/mL).

Flugestone acetate is metabolised into hydroxylated metabolites, which are excreted in faeces and urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylcellulose (e.g. Klucel E, or equivalent)
Polyethylene glycol 4000
Purified water
Polyester Polyurethane Sponge
Multifilament polyamide string high resistance (1.17 g/Km)

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C in a dry place.
Store the product in its original immediate packaging.

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Once packaging is opened, any unused product should be discarded.

6.5 Nature and composition of immediate packaging

Bags made of polyester/ aluminium/ polyethylene containing 10 sponges, 25 sponges or 50 sponges.

6.6 Special precautions for the disposal of unused medicinal product or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of as toxic waste, do not throw to sewer.

7. MANUFACTURER

Intervet Productions SA
Rue de Lyons
27460 Igoville
France

8. REGISTRATION HOLDER

Intervet Israel Ltd.
Industrial Zone Neve Ne'eman 2
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9. LICENSE NUMBER

157-89-34250-00

Revised in June 2022 according to MoHs guidelines.

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות www.health.gov.il לצורך העלאתו לאתר וניתן לקבלו מודפס על ידי פניה לבעל הרישום Intervet Israel Ltd, פארק התעשיה נווה נאמן הוד השרון 45240 ישראל.

בברכה
גאי וגנר
רוקח ממונה