ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Polyester/ Aluminium/ Polyethylene Bags (10 sponges, 25 sponges and 50 sponges presentations) *[text appearing on label as no carton box will be used)*.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chronogest CR 20mg controlled release vaginal sponge for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Flugestone acetate, 20 mg/sponge.
17,9 mg flugestone equivalent to 20 mg flugestone acetate.

3. PACKAGE SIZE

Polyethylene bag containing 10, 25 or 50 sponges.

4. TARGET SPECIES

Sheep (ewe and ewe lamb).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Vaginal use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Store in the original package.
Store in a dry place.
Once packaging is opened, any unused product should be discarded.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3003

15. BATCH NUMBER

Lot {number}

The product should not be administered by pregnant women or women suspected to be pregnant.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Chronogest CR 20mg controlled release vaginal sponge for sheep

2. Composition

Each sponge contains:

Active substance(s)
17,9 mg flugestone equivalent to 20 mg flugestone acetate.

List of excipients
Hydroxypropylcellulose, 20 mg
Macrogol 4000, 20 mg

White cylindrical polyester polyurethane medicated sponge equipped with string.

3. Target species

Sheep (ewe and ewe lamb).

4. Indications for use

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

5. Contraindications

None.

6. Special warnings

Special precautions for safe use in the target species:
- 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Personal protective equipment consisting of single use gloves should be worn when handling the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women or women suspected to be pregnant.

Direct contact with the skin should be avoided. 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.

Pregnancy and lactation:
The use is not recommended during pregnancy.
Can be used during lactation.

Fertility:
- 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.

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.

Overdose:

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

Major incompatibilities:

None known.

7. Adverse events

Sheep (ewe and ewe lamb):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vaginal discharge[1]

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

The dose is one sponge per animal independent of the body weight, breed, type and season.
For vaginal use using an applicator.

9. Advice on correct administration

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.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Store below 25 °C.
Store in the original package.
Store in a dry place.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems applicable to the veterinary medicinal product concerned.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/3003

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN
Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet Productions S.A.
Rue De Lyons
Igoville
27460
France

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24, Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Gavin Hall
Approved: 17 March 2025