

**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**

MSD Animal Health UK Ltd

**14. MARKETING AUTHORISATION NUMBERS**

Vm 01708/3019

**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 <sup>1</sup>

<sup>1</sup> 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](mailto: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 01708/3019

Not all pack sizes may be marketed.



**15. Date on which the package leaflet was last revised**

October 2023

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

Marketing authorisation holder:

MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

Manufacturer responsible for batch release:

Intervet Productions S.A.  
Rue De Lyons  
Igoville  
27460  
France

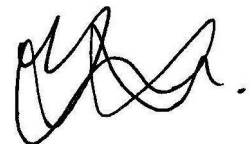
Contact details to report suspected adverse reactions:

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.



Approved: 26 January 2024