

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTAVANCE 20 mg intramammary suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe of 10 ml contains:

Active substance:

Hydrocortisone aceponate ...20 mg

Excipients:

Qualitative composition of excipients and other constituents
Paraffin light liquid
Vaseline codex T5

White to yellowish oily suspension.

3. CLINICAL INFORMATION

3.1 Target species

Lactating cows

3.2 Indications for use for each target species

For the treatment of the inflammatory signs of mild to moderate clinical mastitis.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The veterinary medicinal product does not contain an antimicrobial substance. It is recommended to take a milk sample for bacteriological analysis before the first administration.

Based on the clinical response to treatment and/or milk analysis results, further treatment, including the appropriate antimicrobial(s), may be required, where clinically justified following a benefit risk evaluation by the responsible veterinarian.

In a clinical field trial, two weeks after the last treatment was administered to cows suffering from mild to moderate clinical mastitis, udder inflammation and pain had resolved, and milk quality had returned to normal, in 52.9% of cows treated with the

veterinary medicinal product, compared to 42.1% of cows treated with a placebo. The veterinary medicinal product has only been investigated for the treatment of one affected quarter per cow.

The veterinary medicinal product has not been investigated in cases of severe clinical mastitis, cases with systemic signs or those requiring systemic treatment, where the teat of the affected quarter is visibly damaged, in instances of recurrent clinical mastitis in the same quarter, in cases previously affected by subclinical mastitis in any quarter, or when used concurrently with any antimicrobial, immunomodulatory, or other anti-inflammatory veterinary medicinal product(s).

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Veterinary medicinal product: The active substance of the medicine is potentially pharmacologically active and may be harmful to the unborn child during pregnancy at high doses of exposure.

Avoid skin contact and ingestion, including hand-to-mouth transfers, especially pregnant women.

In case of accidental skin contact, wash the exposed area immediately with soap and water.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Cleaning towel: The cleaning towels provided with the intramammary product contain isopropyl alcohol which is eye irritant.

Avoid eye contact, including hand-to-eye contacts, with the cleaning towel.

In case of accidental eye contact, rinse immediately with plenty of water. If irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

The cleaning towel is flammable. Do not use close to an open flame or any other incandescent material. Do not smoke when handling the cleaning towel.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Lactating cows

Very common (>1 animal / 10 animals treated):	Neutrophilia ¹ , Monocytosis ¹ , Eosinopenia ¹ , Hypocortisolaemia ^{1,2} , Hyperglycaemia ¹
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¹ Mild, spontaneously reversible within 6 days of the final treatment, and not associated with clinical signs.

² Only observed after adrenocorticotrophic hormone (ACTH) stimulation test.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The veterinary medicinal product can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramammary use.

The veterinary medicinal product is for use in cows with mild to moderate clinical mastitis. Before administering the veterinary medicinal product, the teats should be thoroughly cleaned and disinfected using a cleaning towel, and care should be taken to avoid contamination of the syringe nozzle.

Administer the full content of one syringe after each milking (approximately every 12 hours) for 1 to 4 consecutive milkings into the affected quarter.

Massage after administration.

Do not milk after treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In an overdose study in dairy cattle (up to 4X the recommended dosage for 3X the recommended maximum duration of treatment), administration of the veterinary medicinal product was associated with changes on some blood haematology (increased neutrophil count, decreased red blood cell count, decreased haematocrit, decreased haemoglobin) and biochemistry parameters (dose-dependent increases in glucose and amylase), reduction of the capacity of production of cortisol, and decreased milk production or composition change. All these pharmacological effects were of low magnitude, non-adverse, and reversible within 6 days of the final treatment.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4 PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG52X

4.2 Pharmacodynamics

The veterinary medicinal product contains the active substance hydrocortisone aceponate. Hydrocortisone aceponate (HCA) belongs to the diester class of the glucocorticosteroids with a potent intrinsic local glucocorticoid activity. The veterinary medicinal product reduces udder inflammation (redness and swelling), pain and discomfort associated with mild to moderate clinical mastitis.

4.3 Pharmacokinetics

After intramammary administration of the veterinary medicinal product (one syringe [20 mg] every 12 hours for 4 administrations), no plasma availability and systemic exposure of hydrocortisone aceponate was observed (hydrocortisone aceponate < LLOQ 0.2 ng/mL). Hydrocortisone aceponate is metabolised to physiologically active corticosteroid compounds related to physiological cortisol. The absorbed physiologically active corticosteroid compounds cause a strong transient suppression of systemic cortisol plasma concentrations for up to 12 hours after treatment. These corticosteroid compounds are expected to follow the same hepatic metabolic pathway as endogenous cortisol with some renal excretion. Hydrocortisone aceponate was quantifiable in milk from the treated quarter up to 24 hours after the last administration (T_{max} 2.5 hours after the last administration; C_{max} 9,550 µg/kg; elimination t_{1/2} 2 hours). Hydrocortisone aceponate was below the limit of quantification (<0.2 ng/mL) in milk from the untreated quarters.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Opaque sterile low-density polyethylene (LDPE) syringe closed with LDPE nozzle cap or dual cap.

Box with 12 or 24 syringes, with 12 or 24 cleaning towels. Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER

Vm 05653/5075

8. DATE OF FIRST AUTHORISATION

13 February 2026

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 25 February 2026