

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Histodine 10 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Chlorphenamine maleate 10 mg
(equivalent to 7.03 mg chlorphenamine)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.0 mg
Propyl parahydroxybenzoate	0.2 mg
Disodium phosphate dodecahydrate	
Sodium dihydrogen phosphate dihydrate	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the symptomatic treatment of conditions associated with histamine release.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not administer via subcutaneous route.

Although intravenous administration has an immediate therapeutic effect, it can have excitatory effects on the CNS. Consequently, administer slowly and interrupt administration for a few minutes if necessary, when using this route.

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

Chlorphenamine can cause sedation. Wash splashes from skin and eyes immediately. Precautions should be taken to avoid accidental self-injection with this drug. Preferably use a guarded needle until the moment of injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data)	Sedation ^a
--	-----------------------

^a Weak effect

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 safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Concomitant use of other antihistamines or barbiturates may boost the sedative effect of chlorphenamine. The use of antihistamines may conceal early signs of ototoxicity caused by some antibiotics (i.e. aminoglycosides and macrolides) and may shorten the effect of oral anticoagulants.

3.9 Administration routes and dosage

Intramuscular or intravenous use.

Intravenous injection should be slow and, if necessary, discontinued for a few minutes (see 3.5).

Adult animals:

0.5 mg Chlorphenamine maleate /kg bodyweight (equivalent to 5 ml/100 kg bodyweight), once a day for three consecutive days.

Calves:

1 mg Chlorphenamine maleate /kg bodyweight (equivalent to 10 ml/100 kg bodyweight), once a day for three consecutive days.

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

Overdoses up to 4-fold the therapeutic dose have been well tolerated. In very rare cases, local reactions were observed at the injection site. All the reactions were transient and resolved spontaneously.

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: 1 day

Milk: 12 hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QR06AB04

4.2 Pharmacodynamics

Chlorphenamine maleate is a racemic compound classified as an alkyl amine group antihistamine that, due to its chemical characteristics, is able to bind to the H1 receptor present on the cell membrane and therefore compete with the natural endogenous ligand for the same site. Receptor occupation by chlorphenamine maleate does not, in itself, induce pharmacological responses, but significantly inhibits those induced by histamine. On the basis of these observations, chlorphenamine maleate behaves as a direct or reversible competitive receptor antagonist. Chlorphenamine maleate is not able to inhibit the synthesis or release of histamine.

4.3 Pharmacokinetics

After intravenous administration the medicinal product's plasma concentration drops from 36 ng/mL to the method's limit of detection (1 ng/mL) 24 hours after

administration. The calculated elimination half-life ($T_{1/2\beta}$) is 2.11 hours, the mean residence time (MRT) is 2.35 hours, total clearance (Cl_B) 1.315 L/kg/h and the volume of distribution (V_d) just over 3 L/kg. Following intramuscular administration, peak concentration ($C_{max} = 142$ ng/mL) is reached in 28 minutes (T_{max}). Plasma concentrations then drop rapidly to reach values of 60 and 12 µg/kg after 2 and 8 hours before dropping below the limit of quantification (1 µg/kg) 24 hours after treatment. MRT and bioavailability were 3.58 hours and 100%, respectively. The compound and its metabolites are excreted primarily via the kidneys in urine, with a small amount in unmodified form and the majority as a breakdown product, almost completely, within 24 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 56 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage precautions.
Store in the original package in order to protect from light.

5.4 Nature and composition of immediate packaging

Clear Type II glass vials and polypropylene vials containing 100 ml or 250 ml, closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 41821/4041

8. DATE OF FIRST AUTHORISATION

06 July 2017

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

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 17 July 2026