AGENCE NATIONALE DU

MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

14 RUE CLAUDE BOURGELAT – PARC D'ACTIVITES DE LA GRANDE MARCHE JAVENE – CS 70611 – 35306 FOUGERES

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

VeteCorH 1000 IU/ml lyophilisate and solvent for solution for injection for cattle, horses, sheep, goats, pigs, cats and dogs [AT, BE, BG, DE, ES, FR, HR, HU, IE, LT, LV, NL, PL, PT, RO, UK]

VeteCor H 1000 IU/ml lyophilisate and solvent for solution for injection for cattle, horses, sheep, goats, pigs, cats and dogs [IT]

VeteCorH 1000 IU/ml lyophilisate and solvent for solution for injection for cattle, horses, sheep, goats, pigs, cats and dogs	FR/V/0467/001/DC
LABORATORIOS CALIER	DCP
Publicly available assessment report	

PRODUCT SUMMARY

EU procedure number	FR/V/0467/001/DC
Name, strength and pharmaceutical form	VeteCorH 1000 IU/ml lyophilisate and solvent for solution for injection for cattle, horses, sheep, goats, pigs, cats and dogs [AT, BE, BG, DE, ES, FR, HR, HU, IE, LT, LV, NL, PL, PT, RO, UK] VeteCor H 1000 IU/ml lyophilisate and solvent for solution for injection for cattle, horses, sheep, goats, pigs, cats and dogs [IT]
Applicant	LABORATORIOS CALIER S.A Calle De Barcelones 26 Poligono Industrial El Ramassa Les Franqueses Del Valles 08520 Barcelona SPAIN
Active substance(s)	GONADOTROPHIN, CHORIONIC PH. EUR.
ATC vetcode	QG03GA01
Target species	Cattle, horses, sheep, goats, pigs, cats and dogs
Indication for use	Cattle, horses, pigs, sheep, goats, dogs and cats: • In females: induction of ovulation (e.g. follicular cysts, delayed ovulation, anovulation). • In males: stimulation of libido Foals, puppies: Treatment of inguinal cryptorchidism.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

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SUMMARY OF ASSESSMENT

Legal basis of original application*	Hybrid application in accordance with Article 19 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	CHORULON 5000 LYOPHILISAT ET SOLVANT POUR SOLUTION INJECTABLE
Marketing authorisation holder	Intervet (MSD Animal Health)
MS where the RP is or has been authorised	FRANCE
Marketing authorisation number EU procedure number	FR/V/8336311 5/1983 FR/V/0467/001/DC
Date of authorisation	02-11-1983
Date of completion of the original decentralised procedure	23/04/2025
Concerned Member States for original procedure	AT BE BG DE ES HR HU IE IT LT LV NL PL PT RO UK(NI)
Concerned Member States for subsequent recognition procedure	/
Withdrawn CMS during original decentralised procedure	/

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

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The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains in a vial 5000 UI of chorionic gonadotrophin and the excipients mannitol, sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium hydroxide, phosphoric acid and water for injections. The solvent for reconstitution contains the excipients sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium hydroxide, phosphoric acid and water for injections.

The containers are vials of colourless glass, Type I (European Pharmacopoeia).
The choice of the formulation is justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

The selection of the manufacturing process of the active substance and the finished product is explained.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at licensed manufacturing sites.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substance is human gonadotrophin chorionic, an established active substance described in the European Pharmacopeia. The active substance is extracted in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided. Excipients are controlled according their respective European Pharmacopoeia monographs.

Scientific data have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control tests carried out on isolated intermediates during the manufacturing process

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E. Control tests on the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production sites have been provided demonstrating compliance with the specification.

F. Stability tests

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological studies

See part 4.

Toxicological studies

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

Other studies

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

Observations in humans

The applicant has provided bibliographical data on hCG human medicines.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the active substance is a natural substance, the use of which will not alter the concentration or distribution of the substance in the environment.

B. Residues documentation

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Residue tests

No residue depletion studies were conducted as bioequivalence of the product and the reference product was demonstrated.

Maximum Residue Limits

a. Active Substances

The active substance, Chorionic gonadotropin, is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010, as follows

HUMAN CHORIONIC GONADOTROPHIN (natural HCG and its synthetic analogues) HUMAN CHORION GONADOTROPHIN (NO ADI)						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry	37/2010 of 22.12.2009

b. Excipients

The MRL status of excipients listed in section 2 of the SPC is indicated in the following table

Excipient	**MRL status**
Mannitol	Table 1, all species, no MRL required, No ADI.
Sodium dihydrogen phosphate dihydrate (E339 (i))	*
Disodium phosphate dehydrate (E339 (ii))	*
Sodium hydroxide (E524)	*
Phosphoric acid, concentrated (E338)	*

*Covered with food additives (substance with a valid E number approved as additives in foodstuffs for human consumption)

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

A. Pre-Clinical Studies

Pharmacological studies

Given the legal basis of this application for a biological product and the claim of bioequivalence between candidate and the reference product, the omission of pharmacodynamics/pharmacokinetics data is considered acceptable, as this information may be extrapolated from the reference product. The bioequivalence was demonstrated according to the section 7.1 of the bioequivalence guideline EMA/CVMP/016/2000-Rev4*).

Tolerance in the target species of animals

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

B. Clinical trials

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As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.