Institute for State Control of Veterinary Biologicals and Medicines
Hudcova 56a
621 00 Brno
Czech Republic
(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bonharen IVN 10 mg/ml solution for injection

MODULE 1

PRODUCT SUMMARY

EU Procedure number	CZ/V/0163/001/MR
Name, strength and pharmaceutical form	Bonharen IVN 10 mg/ml solution for injection
Applicant	Contipro a.s., Dolní Dobrouč 401, 561 02, Czech Republic
Active substance(s)	SODIUM HYALURONATE
ATC vet code	QM09AX01
Target species	Horses, dogs
Indication for use	For the treatment of joint diseases associated with non-infectious synovitis.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Article 13 (1) Generic application
Date of completion of the original mutual recognition	23/10/2019
Date product first authorised in the Reference Member State (MRP only)	04/07/2018
Concerned Member States for original procedure	AT-BE-HU-IE-SK

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species.
The product 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 claims for this product are equivalent to those of the reference product.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product is intended as solution for injection containing 10 mg of sodium hyaluronate per 1 ml as active ingredient and excipients sodium chloride and water for injection.

The container/closure system consists of 6 ml glass vials (hydrolytic type I) closed with bromobutyl rubber stoppers secured with flip-off aluminium cap. Vials are packed in a paper box.

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

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. Process validation was conducted with full-scale batches.

C. Control of Starting Materials

The active substance is sodium hyaluronate, an established active substance described in the European Pharmacopoeia. The active substance is manufactured 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.

Certificate of suitability issued by the EDQM have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products

Not applicable.

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 product.

Satisfactory validation data for the analytical methods have been provided.

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

F. Stability

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 product throughout its shelf life when stored under the approved conditions.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

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 product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. 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 and the product is designed for individual treatment of horses and dogs.

The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

The application for authorization of the veterinary medicinal product Bonharen IVN 10 mg/ml solution for injection (holder Contipro a.s., CZ) has been submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference veterinary medicinal product is Bonharen Intravenous 10 mg/ml solution for injection, holder Contipro a.s., CZ, authorisation number 96/045/00-C.
The generic product has the same pharmaceutical form as the reference product, the same qualitative and quantitative composition of active substance and the same qualitative composition in terms of excipients.

Residue Studies

No residue depletion studies were provided.

MRLs

According to the Annex (Table I) Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, following MRL status have been established for:

Pharmacologically active substance	**Marker residue**	**Animal species**	**MRL**	**Target tissues**	**Other provisions**	**Therapeutic classification**
Hyaluronic acid	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry
Sodium chloride	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry
Aqua for	Substance mentioned in the list of substances out of scope Regulation (EC) No.					

injectione	470/2009

Withdrawal Periods

The withdrawal periods corresponds to the withdrawal periods which are authorized for the reference product.

Withdrawal period(s):
Horses: Meat and offal: Zero days
Milk: Zero hours

IV. CLINICAL ASSESSMENT (EFFICACY)

The application for authorization of the veterinary medicinal product Bonharen IVN 10 mg/ml solution for injection (holder Contipro a.s., CZ) has been submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference veterinary medicinal product is Bonharen Intravenous 10 mg/ml solution for injection, holder Contipro a.s., CZ, authorisation number 96/045/00-C.
The generic product has the same pharmaceutical form as the reference product, the same qualitative and quantitative composition of active substance and the same qualitative composition in terms of excipients.
Details on pharmacodynamics/pharmacokinetics/tolerance in the target species, have been sufficiently described in the reference product, no further documentation is needed.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

MODULE 4

POST-AUTHORISATION ASSESSMENTS

ÚSKVBL
Hudcova 56a
621 00 Brno-Medlánky
Česká republika
+420 541 518 210
Datová schránka: ra7aipu
uskvbl@uskvbl.cz
www.uskvbl.cz
19-31229641/0710
35-31229641/0710