Austrian
Federal Office for
Safety in Healthcare
BASG

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Advantage 40 mg Spot-on Solution for Dogs
Advantage 100 mg Spot-on Solution for Dogs
Advantage 250 mg Spot-on Solution for Dogs
Advantage 400 mg Spot-on Solution for Dogs

AT/V/0020/001-4/MR

(Former: UK/V/0108-110/001 and 108/006/MR)

Date: July 2018

Last update: 31/08/2021

Modules 1-3 reflect the scientific discussion for the approval of Advantage. The procedure was finalised on 31/05/2018. For information on changes after this date please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU Procedure numbers	AT/V/0020/001/MR AT/V/0020/002/MR AT/V/0020/003/MR AT/V/0020/004/MR
Name, strength and pharmaceutical form	Advantage 40 mg Spot-on Solution for Dogs Advantage 100 mg Spot-on Solution for Dogs Advantage 250 mg Spot-on Solution for Dogs Advantage 400 mg Spot-on Solution for Dogs
Applicant	Bayer Austria GmbH Herbststr. 6-10 1160 Vienna Austria
Active substance(s)	Imidacloprid
ATC Vetcode	QP53AX17
Target species	Dogs
Indication for use	For the prevention and treatment of flea infestation. For the treatment of biting lice (*Trichodectes canis*) where this has been previously diagnosed by a veterinary surgeon. Fleas are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

MODULE 2

The Summary of Product Characteristics (SPCs) for these products are available on the Product Information Database of the Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	A informed consent application in accordance with Article 13(c) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure.	AT/V/0020/001-3/MR: 07/08/1997 AT/V/0020/004/MR: 25/02/1999
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	Austria

I. SCIENTIFIC OVERVIEW

This is an informed consent application submitted in accordance with Article 13(c) of Directive 2001/82/EC. The quality / safety / efficacy aspects of this product are identical to the medicinal product with regard to which consent is given.

The applicant has provided a detailed description of the pharmacovigilance system, which fulfils the requirements of Directive 2001/82/EC, as amended. Based on the information provided the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in the Community or in a third country.

Advantage Spot-on Solutions contain 40 mg per pipette, 100 mg per pipette, 250 mg per pipette and 400 mg per pipette imidacloprid for the different strengths of product.
The proposed indications for all products are:

For the prevention and treatment of flea infestations and treatment of biting lice (Trichodectes canis) on dogs of less than 4 kg body weight, on dogs of 4 kg up to less than 10 kg body weight, on dogs of 10 kg up to less than 25 kg body weight and on dogs of 25 kg body weight and greater, respectively.
Fleas are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

The proposed dosage and treatment schedules are:

Dog (kg bw)	Product	Number of Pipettes
Less than 4 kg	Advantage 40 mg Spot-on Solution for Small Dogs	1 x 0.4 ml
4 to less than 10 kg	Advantage 100 mg Spot-on Solution for Medium Dogs	1 x 1.0 ml

10 to less than 25 kg	Advantage 250 mg Spot-on Solution for Large Dogs	1 x 2.5 ml
25 to less than 40 kg	Advantage 400 mg Spot-on Solution for Extra Large Dogs	1 x 4.0 ml
40 kg and greater	Advantage 400 mg Spot-on Solution for Extra Large Dogs	2 x 4.0 ml

All dogs should receive a minimum dose of 10 mg Imidacloprid/kg bodyweight.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC.[1] The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTIUENTS

II.A. Composition

The products contain imidacloprid at varying concentrations, and the excipients benzyl alcohol, propylene carbonate and butylhydroxytoluene.
The container/closure system consists of white polypropylene plastic tubes (pipettes) with an integrated seal membrane and polypropylene cap.

II.B. Description of the Manufacturing Method

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

II.C. Control of Starting Materials

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

II.E. Control Tests on the Finished Product

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

II.F. Stability

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II.G. Other Information

This veterinary medicinal product does not require any special storage conditions. Keep the blister in the outer carton.
Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

As this is an informed consent application according to Article 13(c) of Directive 2001/82/EC, results of safety and residues tests were not required.

User Safety

A user risk assessment was not submitted with these applications, because the products are identical to the medicinal product with regard to which consent is given.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:

- This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
- People with known hypersensitivity to imidacloprid should avoid contact with the veterinary medicinal product.
- Avoid contact between the product and skin, eyes or mouth.
- Do not eat, drink or smoke during application.
- Do not massage the application site
- After application, do not stroke or groom animals until application site is dry.
- Wash off any skin contamination with soap and water.
- Wash hands thoroughly after use.
- If the product gets into eyes accidentally, the eyes should be thoroughly flushed with water.
- If skin or eye irritation persists, obtain medical attention.
- If the product is accidentally swallowed, obtain medical attention immediately.

Environmental Safety

Phase I:
In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted. The product will only be used in non-food animals and as a result environmental exposure will be low.

IV. CLINICAL DOCUMENTATION

As these applications are informed consent applications according to Article 13(c) of Directive 2001/82/EC, efficacy studies were not required. The efficacy claims for these products are identical to the medicinal product with regard to which consent is given.

IV.I. Pre-Clinical Studies

Pharmacology

Pharmacodynamics and Pharmacokinetics
In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

Tolerance in the Target Species

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted. Warnings in the SPC reflect those of the medicinal product with regard to which consent is given.

Resistance

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

IV.II. Clinical Documentation

In accordance with Article 13(c) of Directive 2001/82/EC as amended, no data were submitted.

V.OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the products are used in accordance with the Summary of Product Characteristics the benefit/risk profile of these products is favourable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicines Agencies website (www.HMA.eu).
This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Significant changes

Summary of change (Application number)	**Approval date**
Change of RMS from UK to AT	21/08/2018
Change to SPC: “Any collar should be removed prior to application of the product. Prior to re-fitting the collar, the treated area should be visually assessed to ensure it is dry.” (AT/V/xxxx/WS/010)	22/07/2021
No further significant changes until today.	31/08/2021