Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Gerichtstraße 49
13347 Berlin
(Germany)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cartaxx 20mg, 50mg and 100mg chewable tablets for dogs
(Carprofen)

Date: 01 October 2025

PRODUCT SUMMARY

EU procedure number	DE/V/0350/001-003/DC
Name, strength and pharmaceutical form	Cartaxx 20mg, 50mg and 100mg chewable tablets
Applicant	Alfasan Nederland B.V. Kuipersweg 9 3449 JA WOERDEN The Netherlands
Active substance(s)	Carprofen
ATC vetcode	QM 01 AE 91
Target species	Dog
Indication for use	Reduction of inflammation and pain in acute and chronic diseases of the musculoskeletal system (e.g. osteoarthritis). For the reduction of postoperative pain following soft tissue surgery after previous parenteral analgesia.

de

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).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Rimadyl-Kautablette (Chewable tablet) 20 mg, Rimadyl-Kautablette (Chewable tablet) 50 mg and Rimadyl-Kautablette (Chewable tablet) 100 mg
Marketing authorisation holder	Zoetis Deutschland GmbH
Marketing authorisation number EU procedure number	400578.00.00 400578.01.00 400578.02.00
Date of authorisation	17 December 2002
Date of completion of the original decentralised procedure	01 October 2025
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK, UK(NI)
Concerned Member States for subsequent recognition procedure	N/A
Withdrawn CMS during original decentralised procedure	N/A

*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.

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 carprofen as active substance (20/50/100 mg per chewable tablet) and the excipients microcrystalline cellulose, saccharin sodium, vanillin, lactose monohydrate, sodium starch glycolate (type A) and magnesium stearate.

The container/closure system consists of PVC/PE/PVDC-aluminium blisters, each containing 10 tablets, in a cardboard box.

The choice of the formulation and absence of preservative are justified.

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

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 carprofen, an established substance described in the European Pharmacopeia. 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.

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

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

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 VMP.

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 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.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with the reference VMP has been demonstrated, pharmacological and toxicological studies are not required.

The pharmacology and toxicology aspects of this product are similar to the reference product, with the exception of the addition of the excipients microcrystalline cellulose, saccharin sodium and vanillin. The applicant provided an URA including existing data on the toxicity of the active substance as well as information on the excipients, including those that are not present in the reference product.

A. Safety tests

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. In addition, literature data were provided which substantiate that the hypersensitivity reactions to carprofen cannot be ruled out. Furthermore, it was concluded that an unacceptable risk after accidental ingestion refers especially to children and the user warnings were complemented accordingly.

Overall, the following warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP:

“Carprofen is a non-steroidal anti-inflammatory drug. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

Direct skin contact by the user with the active substance should be avoided, as phototoxic reactions may occur in humans or there is a risk of developing a photoallergy, which may persist for years as severe photo/light sensitivity with redness, swelling and blistering of the skin. Laboratory studies have shown photosensitizing properties for carprofen, as well as for other NSAIDs.

Accidental ingestion of the veterinary medicinal product may cause gastrointestinal effects, such as nausea and gastric pain. Care should be taken to avoid accidental ingestion by children. To avoid accidental ingestion, unused tablet parts should be returned to the open blister space and into the cardbox.

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

Wash hands after use."

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 VMP will only be used in non-food animals.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference veterinary medicinal product has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference veterinary medicinal product .

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the veterinary medicinal product 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.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

None