College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Metomotyl 5 mg chewable tablets for dogs
Metomotyl 10 mg chewable tablets for dogs

Date: 11 May 2021 (updated 9 October 2025)

MODULE 1

PRODUCT SUMMARY

Dutch Application numbers	REG NL 126919, 126920
EU Procedure number	NL/V/0334/001-002/DC
Name, strength and pharmaceutical form	Metomotyl 5 mg chewable tablets for dogs Metomotyl 10 mg chewable tablets for dogs
Applicant	Dechra Regulatory B.V. Handelsweg 25, 5531 AE Bladel The Netherlands
Active substance(s)	Metoclopramide hydrochloride
ATC Vetcode	QA03FA01
Target species	Dogs
Indication for use	Alleviation of symptoms such as frequent vomiting, gastric dilatation, chronic gastritis, duodenal-gastric reflux and diarrhoea associated with reduced gastro-intestinal motility.

MODULE 2

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).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	NL/V/0334/001/DC: Hybrid application in accordance with Article 13(1) of Directive 2001/82/EC as amended. NL/V/0334/002/DC: Generic application in accordance with Article 13(3) of Directive 2001/82/EC as amended
Date of completion of the original decentralised procedure	28th of April 2021
Concerned Member States for original procedure	AT, BE, DE, DK, EE, FI, FR, HR, NO, PL, SE, SI.

I. SCIENTIFIC OVERVIEW

Metomotyl 5 mg, 10 mg chewable tablets for dogs are produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that these products can be safely used in the target species; the slight reactions observed are indicated in the SPC.
Metomotyl 5 mg, 10 mg chewable tablets for dogs are safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of these products were demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

The quality, safety and efficacy aspects of Metomotyl 5 mg, 10 mg chewable tablets for dogs are based on bioequivalence with the Reference Product Metoclopramide hydrochloride 10 mg tabletten voor honden REG NL 5110, and the EU Reference Product Metomotyl 10 mg tabletten voor honden REG NL 117484.
Warnings statements and precautions are adopted from the (EU) Reference Product.
Additional statements have been added, based on increased knowledge and the current state of science. Adverse events and contraindications are indicated in the SPC.

II. QUALITY ASPECTS

A. Composition

The tablets contain 5 mg and 10 mg Metoclopramide hydrochloride and the following core excipients: Lactose, Croscarmellose sodium, Magnesium stearate, Chicken flavour and Yeast (dried)
The tablets are cross scored and meant to be broken into equal halves or quarters.
The products are packed in OPA/ALU/PVC//ALU blisters, each containing 10 tablets.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.
A bioequivalence study is waived for the generic Metoclopramide hydrochloride 10 mg

chewable tablets. The 5 mg tablets fulfil the requirements of the biowaiver for strengths.

B. Method of Preparation of the Product

These products are manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

These products are manufactured using conventional manufacturing techniques. However, suitable pre-approval validation results on two small production batches have been provided.

The tests performed during production are described.

C. Control of Starting Materials

The active substance Metoclopramide hydrochloride is an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

A CEP procedure has been employed. The copy of the CEP provided represents the current version.

The active substance specification is considered adequate to control the quality of the material from the supplier. Batch analytical data demonstrating compliance with this specification have been provided.

All excipients are in conformity with the Ph.Eur. requirements with the exception of Chicken flavour and Yeast extract which have been adequately specified.

The packaging is in conformity with the Ph. Eur. and EU Food Directive.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies.

The Magnesium stearate is of vegetable origin. In regard to Chicken flavour and Yeast extract a BSE/TSE declaration is provided.

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. Relevant tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of these products.

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

According to the statement on the CEP the claimed retest period of 60 months can be granted.

Stability data on the finished product has been provided in accordance with applicable European guidelines. According to the stability results provided the claimed shelf life of 3 years and the In-use shelf life of 3 days can be granted.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application (10 mg tablets) respectively a hybrid application (5 mg tablets) according to Article 13, and bioequivalence with the (EU) Reference Product can be assumed, results of toxicological, pharmacological and clinical tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the (EU) Reference Product and are adequate to ensure safety of these products to users / the environment / consumers.

Additional statements have been added, based on increased knowledge and the current state of science. Adverse events, warnings and contraindications are indicated in the SPC.

III.A Safety Testing

User Safety

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

Combined with increased knowledge and the current state of science, warnings and precautions as listed on the product literature are adequate to ensure safety to users of these products.

Environmental Risk Assessment

Phase I

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

The environmental risk assessment can stop in Phase I because these products are intended for use in dogs and a Phase II assessment is not deemed necessary.

These products are not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application (10 mg tablets) respectively a hybrid application (5 mg tablets) according to Article 13, and bioequivalence with the (EU) Reference Product can be assumed, efficacy studies are not required. The efficacy claims for these products are equivalent to those of the Reference Product.

Tolerance in the Target Species of Animals

In addition to the above, based on increased knowledge and the current state of science, warning statements and precautions have been added to the product literature ensuring safety to the target animals. Adverse events, warnings and contraindications are indicated in the SPC.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when these products are 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 these products for humans and the environment is acceptable.

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 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 these products.

Summary of change (Application number)	**Section updated in Module 3**	**Approval date**
Quality NL/V/0334/A/002/G - F.II.b.3 a) - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process. - F.II.b.3 h) - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate or bulk product. - F.II.b.1 c) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products.	-	22 June 2025
Quality Consequential VNRA variations - B.26. c) - Changes to the quality part of the dossier – Change in the batch size (including batch size ranges) of the finished product. - B.20 - Changes to the quality part of the dossier – Replacement or addition of a primary packaging site of a non-sterile finished product. - B.21 - Changes to the quality part of the dossier - Replacement or addition of a secondary packaging site of a finished product. - B.24 - Changes to the quality part of the dossier - Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product.	-	22 June 2025

Quality NL/V/0334/001-002/A/003 - F.II.f.1.a.1 - To extend the shelf-life of the finished product as packed for sale from 30 months to 3 years	yes	9 October 2025