



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

POST AUTHORISATION INFORMATION
FOR A VETERINARY MEDICINAL PRODUCT

Synulox 50 mg tablets for dogs and cats
Synulox 250 mg tablets for dogs and cats
Synulox 500 mg tablets for dogs

Date: 13 October 2025

Synulox 50 mg, 250 mg, 500 mg tablets	DE/V/0391/001-003
Zoetis	MRP
POST AUTHORISATION INFORMATION FOR A VETERINARY MEDICINAL PRODUCT	

PRODUCT SUMMARY

EU procedure number	DE/V/0391/001-003
Name, strength and pharmaceutical form	Synulox 50 mg tablets for dogs and cats Synulox 250 mg tablets for dogs and cats Synulox 500 mg tablets for dogs
Marketing Authorisation Holder	Zoetis Deutschland GmbH Leipziger Platz 18 10117 Berlin Germany
Active substance(s)	Amoxicillin trihydrate Potassium clavulanate
ATC vetcode	QJ01CR02
Target species	<u>Synulox 50 mg & Synulox 250 mg:</u> Dogs and cats <u>Synulox 500 mg:</u> Dogs
Indication for use	<u>Synulox 50 mg & Synulox 250 mg:</u> Dogs: For the treatment of - Skin infections (including deep and superficial pyoderma). - Soft tissue infections (including anal sacculitis and abscesses). - Urinary tract infections. - Respiratory infections. - Intestinal infections. - Periodontal infections in addition to mechanical or surgical periodontal therapy. Cats: For the treatment of - Skin infections (including superficial pyoderma). - Soft tissue infections (including abscesses). - Urinary tract infections. - Respiratory infections. - Intestinal infections. - Periodontal infections in addition to mechanical or surgical periodontal therapy.

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	<u>Synulox 500 mg:</u> For the treatment of - Skin infections (including deep and superficial pyoderma). - Soft tissue infections (including anal sacculitis and abscesses). - Urinary tract infections. - Respiratory infections. - Intestinal infections. - Periodontal infections in addition to mechanical or surgical periodontal therapy.
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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*	Full application (Article 12(3) of Directive No 2001/82/EC)
Dossier substantiated by proprietary data	Qualified for data protection: no ¹
Date of completion of the original mutual recognition procedure	SPC harmonisation of reference VMP with subsequent transfer of national authorisations to mutual recognition procedure (MRP). Date of MRP transfer: 01/12/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	05/12/2003
Concerned Member States for original procedure	Synulox 50 mg & Synulox 250 mg: BE, BG, CY, CZ, EE, FI, FR, GR, HU, IE, IT, LV, LT, LU, NL, NO, PL, PT, RO, SK, SI, ES, SE, XI Synulox 500 mg: BE, CY, CZ, EE, FI, FR, GR, HU, IT, LV, LT, LU, NL, NO, PL, PT, SK, SI, ES, SE, XI
Concerned Member States for subsequent recognition procedure	Not applicable.
Withdrawn CMS during original mutual recognition procedure	Not applicable.

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. Additionally, detailed information on protection periods has only been published in puAR since 09.02.2026.

¹ Please note that the start of the period of protection is the date when the first marketing authorisation was granted in the Union (please refer to Guidance to Applicants – Veterinary medicinal products C/2024/1443 as amended by C/2024/90009 Corrigendum to Commission Notice – Guidance to Applicants – Veterinary Medicinal Products). For further information, please check the UPD.

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GENERAL INFORMATION

Due to the date of authorisation of this product no public assessment report is available. Please be referred to the post authorisation procedures section.

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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 are important for the quality, safety or efficacy of the VMP and which have been made after 27 January 2022. Please be aware that changes to the product introduced before Regulation (EU) 2019/6 started to apply, will not be listed below.

Please note that for VMPs that were transferred to MRP after SPC harmonisation, the section “Changes to Part 2 of the dossier (quality)” contains only information on significant changes important to quality which have been made starting from Part II harmonisation, whereas section “Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)” contains only information on significant changes important to safety or efficacy of the VMP which have been made starting from the respective SPC harmonisation procedure.

Sequence of significant variations

Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	End of procedure
F.II.f.1.a.2 - QUALITY CHANGES - Finished product - Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After first opening (supported by real time data) F.II.b.3.z - QUALITY CHANGES - Finished product - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of the CMDv guidance on the details of the classification of variations requiring assessment F.V.b.1.c - QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Harmonisation of the quality dossier - Harmonisation of the quality dossier for the same purely national products and/or the same products approved in MR/DC procedures which are owned by the same MAH not participating in a former union interest referral procedure or SPC harmonisation procedure (DE/V/xxxx/WS/183)	20/05/2025

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Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	Supporting information	End of procedure
SPC harmonisation of a reference VMP in accordance with article 70 of Regulation (EU) 2019/6: (DE/V/xxxx/001-003/SPC/002)	Appropriate existing data (proprietary/bibliographic) to support aspects that go beyond the common denominator in accordance with Article 8 of Regulation (EU) 2019/6 for harmonisation of dossier in RMS and CMS. Qualified for data protection: no ²	13/10/2025

² Please note that the period of protection starts counting from the date of the first amendment of the marketing authorisation in the EU (please refer to Guidance to Applicants – Veterinary medicinal products C/2024/1443 as amended by C/2024/90009 Corrigendum to Commission Notice – Guidance to Applicants – Veterinary Medicinal Products).