Federal Office of
Consumer Protection
and Food Safety

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Gerichtstr. 49, D-13347 Berlin

POST AUTHORISATION INFORMATION FOR A VETERINARY MEDICINAL PRODUCT

Tetra Veyxin LA 200 mg/ml

PRODUCT SUMMARY

EU procedure number	Not applicable
Name, strength and pharmaceutical form	Tetra Veyxin LA 200 mg/ml
Marketing Authorisation Holder	Veyx-Pharma GmbH Söhreweg 6 D-34639 Schwarzenborn
Active substance(s)	Oxytetracyclin $2H_2O$
ATC vetcode	QJ01AA06
Target species	Rind, Schaf, Schwein
Indication for use	Zur Behandlung von folgenden Infektionen bei Rindern, Schafen und Schweinen: Anaplasmose, Atemwegsinfektionen, Keratokonjunktivitis und Metritis, Mastitis, Agalaktie (MMA-Syndrom der Sau), akute Eperythrozoonoseanfälle (Schwein) und ansteckendes Verlammen (Chlamydienabort beim Schaf)

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*	Antrag aufgrund einer in Kenntnis der Sachlage erteilten Einwilligung (Zustimmung Vorantragsteller, Informed Consent)
Date of completion of the original <mutual recognition> <decentralised>procedure	Not applicable
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Not applicable
Concerned Member States for subsequent recognition procedure	Not applicable
Withdrawn CMS during original <mutual recognition> <decentralised><subsequent 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

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.

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 affect the referenceability and protection period of the dossier or parts of the dossier 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 as well as variations without affecting the referenceability or protection period of the dossier will not be listed below.

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

Summary of change (Application number)	Supporting information	Approval date
G.I.7.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one Indication for use: *Zur Behandlung von folgenden Infektionen bei Rindern, Schafen und Schweinen: Anaplasmose, Atemwegsinfektionen, Keratokonjunktivitis und Metritis, Mastitis, Agalaktie (MMA-Syndrom der Sau), akute Eperythrozoonoseanfälle (Schwein) und ansteckendes Verlammen (Chlamydienabort beim Schaf)* (Application dated 21/09/2023)	Reference to proprietary data of a linked VMP: Oxipra – 20 L.A. Solution for Injection 200 mg/g Solution for injection Laboratorios Hipra, S.A., Avda. La Selva, 135, 17170-Amer (Girona), Spain	10/05/2024