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

Aciphen Kompaktat

Date: 13.04.2023

PRODUCT SUMMARY

EU procedure number	Not applicable
Name, strength and pharmaceutical form	Aciphen Kompaktat, 1000 mg/g, Granulat zum Eingeben
Marketing Authorisation Holder	Bela-Pharm GmbH & Co. KG Lohner Straße 19 D-49377 Vechta
Active substance(s)	Amoxicillin-Trihydrat
ATC vetcode	QJ01CA04
Target species	Rind (Kalb, noch nicht wiederkäuend), Schwein
Indication for use	Zur Behandlung von folgenden durch grampositive und/oder gramnegative Bakterien hervorgerufene Krankheiten: Schweine und Ferkel: - Infektionen der Lunge (außer Ferkel) und der Atemwege - Infektionen des Verdauungsapparates Kälber: - Infektionen des Verdauungsapparates Zur Behandlung von folgenden durch Streptococcus suis hervorgerufene Krankheiten: Schweine und Ferkel: - Meningitis - Arthritis - Sekundäre Infektionen

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*	Application based on bibliographic data
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Withdrawn CMS during original 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 - Addition of the following indication in pigs: Treatment of meningitis, arthritis and secondary infections caused by bacteria susceptible to amoxicillin. (Application dated 13/04/2023)	Reference to proprietary data of a VMP: Paracillin SP 800 mg/g peroralni prašek za piščance in prašiče 800 mg/g - Oral powder - Intervet International B.V. - Slovenia	12/2023