CHEPLAPHARM *Arzneimittel GmbH*

CHEPLAPHARM Arzneimittel GmbH (Office) Ziegelhof 24 17489 Greifswald Germany

To whom it may concern

Greifswald, 2020-03-18

Ref: Declaration of Equivalence between common layout English-French-Arabic (EFA) and the layout of the reference country United Kingdom (UK) for the medicinal product Konakion 2 mg/0.2 ml

Dear Madam or Sir,

We, the undersigned company CHEPLAPHARM Arzneimittel GmbH seated at Ziegelhof 24, 17489 Greifswald, Germany would like to report the following differences between the above-mentioned layouts for your information. Please refer to the table below for more details.

Description Layout	EFA Layout	UK Layout
Label (Ampoule)		
Product name	Konakion® MM paediatric	Konakion MM Paediatric
INN	Phytomenadione	Phytomenadione / Vitamin K_1
Colour	White background with pink bar	White background with pink bar
Font size	3 pt	4 pt
MAH and manufacturer details	Made for CHEPLAPHARM Arzneimittel GmbH, Greifswald, Germany by CENEXI SAS, Fontenay-sous-Bois, France	CHEPLAPHARM Arzneimittel GmbH
Method of administration	oral/i.m./i.v.	Solution for injection or oral administration
Variable data	EXP, Lot, MFD	EXP, Batch
Carton (outer packaging)		
Product name	Konakion® MM paediatric	Konakion MM Paediatric 2 mg/0.2 ml
INN	Phytomenadione	Phytomenadione / Vitamin K_1
Colour	White background with pink bar	White background with pink bar
Font size	9 pt	9 pt
Pictogram	No pictogram	Pictogram explaining how to break the ampoules

CHEPLAPHARM Arzneimittel GmbH

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Managing Directors:

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Court of Registry:
Stralsund HRB 5396

Bank Accounts:

Deutsche Bank AG
IBAN: DE34 1307 0000 0227 3332 00 SWIFT-Code: DEUTDEBRXXX
Raiffeisenbank Grävenwiesbach eG
IBAN: DE04 5006 9345 0000 0385 12 SWIFT-Code: GENODE51GWB
UniCredit Bank AG
IBAN: DE44 2003 0000 0616 2047 31 SWIFT-Code: HYVEDEMM300

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Description Layout	EFA Layout	UK Layout
Statement of active substance	1 ampoule = 0,2 ml = 2 mg phytomenadione (vitamine K_1)	Each 0.2 ml ampoule of Konakion MM Paediatric contains 2 mg of phytomenadione (vitamin K_1).
Method of administration	oral/i.m./i.v., For oral use or i.m./i.v. injection	Solution for injection or oral Administration; For intramuscular injection, intravenous injection or oral administration; Oral/Intramuscular/Intravenous
Special Warnings	Medicine: keep out of reach of children	KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Indication	No indication mentioned	No indication mentioned
Pipette for oral application	Not mentioned	5 Oral Dispensers
Excipients	Not mentioned	List of excipients mentioned on carton
Storage conditions	Do not store above 25 °C. Protect from light	Store below 25 °C. Do not freeze Keep ampoules in the carton in order to protect from light
Instructions on use	For paediatric use Dosage and administration: see package insert Do not use if the solution is turbid	The dispensers included in this pack are for oral administration only Use only as directed by a doctor Do not use if the solution is turbid CAUTION: For intramuscular or intravenous injection care is required when calculating and measuring the dose in relation to the baby's weight as errors of 10 times the expected dose are possible
MAH and manufacturer details	Made for CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald, Germany by CENEXI SAS 52 rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France	CHEPLAPHARM Arzneimittel GmbH Ziegelhof 24 17489 Greifswald Germany
Classification for supply	Not mentioned, common layout	POM
MAH number	Not mentioned, common layout	PL27041/0010

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Description Layout	EFA Layout	UK Layout
Serialisation	Carton contains Serialisation data	Carton contains Serialisation data
Variable data	GTIN, EXP, Lot, MFD, SN	PC, EXP, Batch, S/N
Braille	No braille	konakion mm paediatric 2 mg/0.2 ml
Patient information leaflet (PIL)		
Language	English/French/Arabic	British English
Product name	Konakion® MM paediatric	Konakion MM Paediatric 2 mg/0.2 ml solution for injection or oral administration
Dimensions	210 x 315 mm	315 x 420 mm
Font size	5 pt	10 pt
Contact details for the notification of adverse effects	No pharmacovigilance contact details mentioned, common layout	Local pharmacovigilance contact details mentioned

Please note, that the differences only apply to the general layout, the content of the packaging material was not evaluated for this declaration.

The UK and the EFA product as well as the primary packaging (Ampoule) are identical. Both products are produced to the same formulation and specification, in the same manufacturing site.
The only difference is the additional French and Arabic language of the EFA packaging material. Please take into consideration that if the information provided in the UK and the EFA package leaflet are not identical, the UK package leaflet applies.

The UK package leaflets are available at www.mhra.gov.uk.

Kind regards,

Beate Matzkeit
Manager Regulatory Affairs
CHEPLAPHARM Arzneimittel GmbH

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