



29 December 2020

Medicine Supply Alert Notice

Phytomenadione (Konakion MM Paediatric) 2mg/0.2ml ampoules (Cheplapharm)

Priority: Level 2*

Valid until: until late January 2021

Issue

1. UK licensed Konakion MM Paediatric will be out of stock **until late January 2021**.
2. Supplies of Konakion MM Paediatric in tri-lingual packaging (including English; considered unlicensed in the UK) are available to support during this time. See Additional Information below for further details.

Advice and Actions

3. Where there are insufficient supplies of licensed stock available unlicensed Konakion MM Paediatric may be supplied following appropriate Health Board procedures.
4. Health Boards should consider their position regarding the use of unlicensed Konakion MM Paediatric including supply against a Midwives Exemption. See Additional Information section below for further details.
5. See Additional Information section for ordering advice.

Additional Information

6. Cheplapharm have sourced sufficient Konakion MM Paediatric in EFA (English – French – Arabic) layout which is manufactured in the same facility and to exactly the same formulation and standards as the UK licensed product.
7. Quality assurance colleagues have approved the *Declaration of Equivalence* document in Annex A.
8. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board or local governance procedures. Please see the links below for further information.
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC),
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society

Midwives Exemptions

9. The Department of Health and Social Care (DHSC) has discussed midwife exemptions with their own internal legal team and has advised that unlicensed medicines may be supplied against a Midwives Exemption.
10. The following represents the DHSC's view of the exemptions that might be applicable to the circumstances, but it should not replace the need for Health Boards to consider their own position and take legal advice if necessary:

“There are two kinds of exemptions for midwives in the Human Medicines Regulations (HMRs). One relates to the need for a prescription and that is set out in regulation 235 and Part 1 of Schedule 17 HMRs. These provide that the requirement in regulation 220 that POMs are supplied against a prescription does not apply to the sale or supply by midwives of POMs containing phytomenadione in the course of their professional practice. As this product is a product for parenteral administration, it is a POM by virtue of Part 1, Sch. 1 HMRs, i.e. whether it has a licence or not. Therefore, nothing can be seen in the HMRs that would limit the midwives’ *prescription* exemption to licensed phytomenadione (given by any route).

As to the relevance of a licence for the *assembly or supply* of the product, regulations 3 and 4 HMRs may be applicable, as well as the specials exemption, depending on how the product is sourced and what the midwife does. If the midwife assembles the product into a syringe for injection, this activity would be covered by regulation 3 HMRs as it exempts the midwife from the need for a manufacturing licence for that activity. Again, this assembly could be of a licensed or unlicensed product.

As to how the product is supplied, it might be supplied to the hospital as an unlicensed special if the conditions for such supply are met, or it could be prepared in a hospital pharmacy under regulation 4 HMRs/section 10 of the Medicines Act 1968. Both of those provide potentially lawful supply routes for unlicensed products.”

Ordering information

11. Please also see attached information on Annex B from Neon Healthcare about how to order unlicensed Konakion MM Paediatric 2mg/0.2mL amps via Alliance and Mawdsleys.

- Alliance Healthcare Specials (Alcura) - PIP code: 8021677
 - Description: KONAKION PAED AMP 2MG/0.2ML
 - Email: specials.orders@alliance-healthcare.co.uk
 - Tel: 0344 8544 998/Fax: 08450 518 779
- Mawdsleys Unlicensed - PIP Code: 287334
 - Description: Phytomenadione 2MG/0.2ML AMP
 - Email: unlicensed@mawdsleys.co.uk
 - Tel: 0161 7423304/Fax: 0161 7423444

Enquiries

12. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).

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 CENEX! SAS, Fontenay-sous-Bois, France	CHEPLAPHARM Arzneimittel GmbH
Method of administration	oral/i.m./i.v.	Solution for injection 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	9pt
Pictogram	No pictogram	Pictogram explaining how to break the ampoules

CHEPLAPHARM Arzneimittel GmbH

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Edeltraud Lafer, MIE (COO)
Jens Rothstein, M.A. (CFO)

Court of Registry:

Stralsund HRB 5896

Bank Accounts:

Deutsche Bank AG
IBAN: DE34 1307 0000 0227 3332 00 SWIFT-Code: DEUTDE33XXX
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: HYVEDE33M300

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 Konaktion 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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IBAN: DE44 2003 0000 0616 2047 31 SWIFT-Code: HYVEDE33XXX

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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UniCredit Bank AG
 IBAN: DE44 2003 0000 0616 2047 31 SWIFT-Code: HYVEDEMM300



**Current situation regarding KONAKION SOL FOR INJ AMP 2MG/0.2ML (2mg phytomenadione in 0.2ml).
1st October 2020**

As you will be aware there will be a short out of stock situation of the UK licensed product KONAKION SOL FOR INJ AMP 2MG/0.2ML (2mg phytomenadione in 0.2ml). Alliance Specials & Mawdsleys Unlicensed have worked with Neon Healthcare Ltd (commercial representative in UK of Cheplapharm, the MA holder) to list an unlicensed imported Konakion 2mg to help maintain supply to the customer. This product is manufactured in the same facility and to exactly the same formulation and standards as the UK licenced product. It is tri-lingual, including English. QC release documentation including QP certified release is available.

The unlicensed product is on order and expected to be in stock at Alliance Specials and Mawdsleys Unlicensed by November 1st 2020. The unlicensed product will only be in place until the UK licensed product is back in stock, currently estimated to be by beginning of December 2020. We are making you aware ahead of the unlicensed product being available to give you time to amend any ordering processes.

Konakion 2mg Unlicensed Special details:

Batch: F3031F02

Expiry: 10/2022

Layout: English – French - Arabic

How to obtain the Unlicensed Product

- **Alliance Healthcare (Alcura)**

The Unlicensed product will be held in Alcura and will be accessible from Alliance Healthcare Specials. The contact details to acquire the product are below. There will be no restrictions on the product to customers and the stock will be delivered on a next day delivery service.

This product should also be available via your PMR depending on when your provider has been updated. If you are struggling to find the unlicensed product, please use the below order details.

PIP code: 8021677

Description: KONAKION PAED AMP 2MG/0.2ML

Customers will be able to order this via:

Email: specials.orders@alliance-healthcare.co.uk

Telephone Number: 0344 8544 998

Fax Number: 08450 518 779





- **Mawdsleys Unlicensed**

Orders with Mawdsleys Unlicensed can be placed via EDI, or email to unlicensed@mawdsleys.co.uk

PIP Code: 287334

Description: Phytomenadione 2MG/0.2ML AMP - packs 5

There will not be an alert when orders are placed on the licensed system – Mawdsleys usually notify that stock is going on back order - customers can then cancel the back order, and send an order instead to unlicensed.

If you have any further questions, please contact:

Mawdsleys Unlicensed

Tel: 0161 7423304

Fax: 0161 7423444

web: www.mawdsleys.co.uk

