12 February 2025

KONAKION MM Paediatric 2mg/0.2mL solution for injection: Temporary supply of overseas product

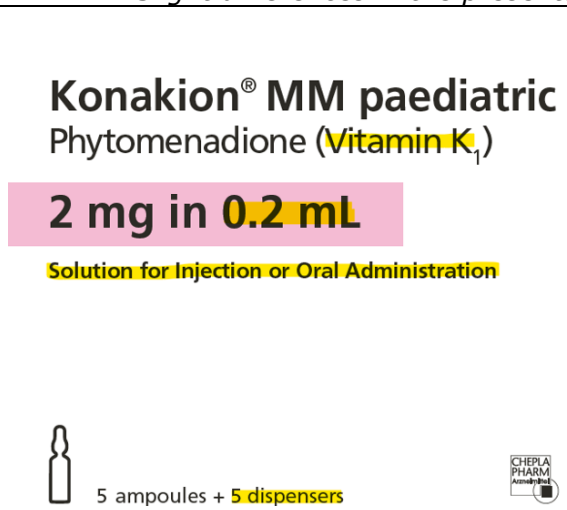
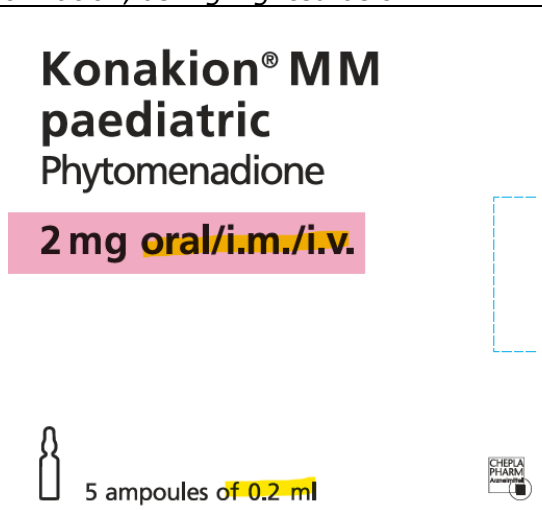
This information is being sent in agreement with Medsafe.

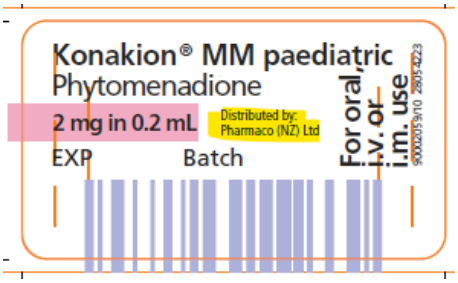
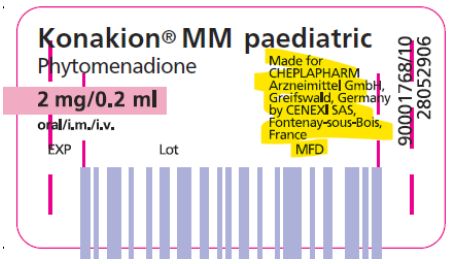
Dear Healthcare Professional,

Konakion MM Paediatric (phytomenadione) 2mg/0.2mL is indicated for Prophylaxis and treatment of haemorrhagic disease in the newborn.

Due to a temporary supply shortage of Konakion MM Paediatric, Pharmaco (NZ) Ltd will be supplying one batch of an overseas pack with the following details:
Batch number: F3161F03
Manufacturing date: 01/2024
Expiry date: 01/2026

This overseas labelled product has the same formulation, concentration, volume, dosage form and manufacturer as the NZ product.
Please find a comparison of the proposed overseas pack with the NZ product labelling below:

Current NZ packaging	Overseas packaging
Carton front panel *Slight differences in the presentation of information, as highlighted below*	
	
Side of carton *NZ distributor details are not present on the overseas pack*	
	

Current NZ packaging	Overseas packaging
Carton back panel *Addition of package insert and French text in the overseas pack*	
For the prevention and treatment of haemorrhagic (bleeding) diseases in newborn babies Contains no antimicrobial agent. Use once only and discard any residue Further information about this medicine is contained in the Consumer Medicine Information (CMI), which is available at www.medsafe.govt.nz Store below 25 °C, protect from light Do not use if the solution is turbid Each ampoule contains 2 mg phytomenadione (Vitamin K_1) in 0.2 mL of solution 4 260095 682420	For oral use or i.m./i.v. injection For paediatric use Medicine: keep out of reach of children Dosage and administration: see package insert Do not store above 25 °C. Protect from light Do not use if the solution is turbid Pour usage oral ou injection i.m./i.v. Pour usage pédiatrique Médicament: tenir hors de la portée des enfants Posologie et emploi: voir notice d'emballage A conserver à une température ne dépassant pas 25 °C et à l'abri de la lumière Ne pas utiliser si la solution est trouble 1 ampoule = 0,2 ml = 2 mg phytomenadione (vitamine K_1) 4 260095 681805
Ampoule label *NZ distributor details are not present on the overseas pack*	
	

This overseas pack also contains a package insert (which is not present in the current NZ pack). This package insert contains additional information to what is in the currently approved New Zealand Datasheet.

Please be advised that the dosage and indications remain the same as currently approved in NZ, and doctors and patients should ***disregard*** the information on dosage, administration and indications in the package insert and refer to the New Zealand approved Datasheet, which is available via the Medsafe website https://www.medsafe.govt.nz/profs/datasheet/k/Konakiontabinjoralsoln.pdf

If you have any medical enquiries or would like further information, please contact Pharmaco (NZ) Ltd via safety@pharmaco.co.nz or phone 0800 80 4079.

Any information regarding adverse events should be reported to Medsafe via the following link: https://pophealth.my.site.com/carmreportnz/s/

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