Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

2nd February 2024

Dear [redacted]

FOI 24/023 and FOI 24/090

Thank you for your email dated Monday 8th January 2024 where you requested details of any reported adverse reactions to "Konakion MM Paediatric 2 mg/0.2 ml Active Ingredient: phytomenadione Company: [redacted] Ltd ATC code: B02BA01".

We have also received your follow-up request dated Monday 22nd January 2024 where you requested:

- Details of all side-effects including adverse reactions and long-term side effects.
- Details of whether there is black box warning on this product.

Please note, reporters are not mandated to provide details of the specific product they received when submitting a Yellow Card; some may only provide details at the substance level, others may only provide a brand name. Furthermore, reporters are able to provide details of the strength when reporting to the Yellow Card scheme, however, this is not mandatory, and reports are often made without details of the strength of the product. This information is collected in a free text field and therefore entries within that field may vary between reports.

In order to provide a response to your first query, a search was completed for all reports of suspected side effects to all Konakion products, for which we located **116** cases. These cases were then filtered to remove any cases that did not refer to a paediatric product or strength of 2 mg/0.2 ml as well as those referring to adult patients. I can therefore confirm that up until the 26th January 2024, the MHRA has received **52** UK ADR reports of suspected side effects to 2 mg/0.2 ml "Konakion" or "Konakion MM" in paediatric patients.

Please find attached the Drug Analysis Print (DAP) for all suspected side effects to 2 mg/0.2 ml “Konakion” or “Konakion MM” in paediatric patients. The print contains information on all the UK spontaneous ADR reports received through the Yellow Card scheme up to and including 26/01/2024. The attached DAP guidance sheet provides you with further information on how to interpret the print.

It is important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

To answer your query regarding long term side effects, Section 4 of the Product Information Leaflet (PIL) lists all known possible side effects for a medicine or vaccine. You can view the PIL for Konakion MM Paediatric 2 mg/0.2 ml here.

In your final query, you asked whether Konakion products have a black box warning. A black box warning is the most serious warning issued by the Food and Drug Administration (FDA) in the United States. Its purpose is to alert people about drug effects that may be dangerous. The US FDA policy for applying black box warnings for some medicines is outside of our remit. The special precautions and warnings for healthcare professionals to be aware of when prescribing this medicine are described in the Summary of Product Characteristics, which is approved by the MHRA and is available here.

I hope the information provided is helpful, but if you are dissatisfied with the handling of the part of your request handled under FOI, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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