



To: All Community Pharmacies in Wales

Cc: Chief Pharmacists, Health Boards
Pharmaceutical Public Health, Public Health Wales
Chief Executive, Community Pharmacy Wales
Director for Wales, Royal Pharmaceutical Society
Director for Wales, General Pharmaceutical Council

Date: 4 August 2015

Our ref: RW/AE

Dear colleague,

PARACETAMOL FOR THE PREVENTION AND TREATMENT OF FEVER POST IMMUNISATION AGAINST MENINGOCOCCAL B DISEASE

Immunisation against meningococcal serogroup B disease (MenB) will be added to the childhood immunisation programme as part of the routine schedule from 1 September 2015. Bexsero[®] is the recommended vaccine for the routine childhood immunisation programme. This letter provides advice for pharmacists on the appropriate use of paracetamol to prevent and treat fever associated with immunisation with Bexsero[®].

The Summary of Product Characteristics (SPC) for Bexsero[®] states infants are at an increased risk of fever when the vaccine is administered at the same time as other routine childhood vaccinations. Given that fever has been a common adverse reaction in trials of Bexsero[®], the Joint Committee on Vaccination and Immunisation (JCVI) has recommended the use of prophylactic paracetamol at the time of immunisation.

When infants are invited for vaccination their parents or guardians will be advised to purchase infant paracetamol suspension (120mg/5ml) prior to vaccination and to give 2.5ml to the child at or as soon as is possible after the vaccine is administered. They will also be advised to give two further doses at 4-6 hourly intervals. This is a change to previous advice where the prophylactic use of paracetamol has not been routinely recommended following immunisation

You will note that, when given to infants of 2 months, the recommended dose regimen of paracetamol of three doses exceeds the post-immunisation licensing restriction on Pharmacy (P) and General Sales List (GSL) paracetamol products, which advise a maximum of two doses. The Commission on Human Medicines (CHM) has been

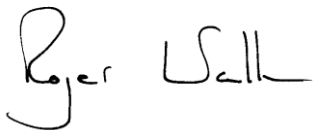
consulted on this matter and is fully supportive of the JCVI's recommendation to use three doses of paracetamol post-immunisation with MenB up to 48 hours following immunisation if required to manage post-immunisation fever in those aged two months old. This recommendation is based on the likelihood that fever is due to immunisation rather than serious infection. Parents and guardians should be advised that this advice does not extend to fever at any other time and in a situation where an infant is otherwise unwell they should not seek delay seeking medical attention.

The CHM has recommended that the Patient Information Leaflets (PILs) in infant paracetamol suspension products should be updated to reflect the JCVI advice in due course.

Given the apparent discrepancy between information in the PIL or on the packaging of infant paracetamol suspension products currently available and the updated advice it is likely that pharmacists will be asked for advice on the appropriate use of prophylactic paracetamol. It is important therefore that pharmacists responding to such requests provide the correct, appropriate, clear and updated advice.

Further details regarding the introduction of Men B immunisation for infants are available in [Welsh Health Circular WHC \(2015\) 040](#).

Yours sincerely

A handwritten signature in black ink that reads "Roger Walker". The signature is written in a cursive style with a large initial 'R' and a long horizontal stroke at the end.

Professor Roger Walker
Chief Pharmaceutical Officer