



12 August 2015

PHE Gateway Number: 2015-285

Dear Colleague

Paracetamol for fever prophylaxis post MenB vaccination

The Joint Committee on Vaccination and Immunisation ([JCVI](#)), which advises UK health departments on immunisation programmes, has recommended the introduction of a national programme for MenB vaccination from 1 September 2015. The MenB vaccine, Bexsero, may cause more fever when given with the other routine infant immunisations at two and four months of age. The JCVI has therefore recommended that 3 doses of paracetamol be given as prophylaxis

This letter provides advice for pharmacists on the appropriate use of paracetamol to prevent and treat fever associated the Men B vaccination. The JCVI has recommended the use of prophylactic paracetamol at the time or shortly after vaccination, with a further two doses every four to six hours thereafter. This advice has been endorsed by the Commission on Human Medicines ([CHM](#)), who advise Ministers on the safety, efficacy and quality of medicinal products, following consultation with the Medicines and Healthcare products Regulatory Agency (MHRA) and Public Health England.

Infant paracetamol suspension 120mg in 5mL on the UK market is currently licensed from 2 months of age and restricted to a maximum of 2 doses to treat post-immunisation fever in 2-3 month olds. This limit was to ensure that fever which may be due to a serious infection in young infants is quickly diagnosed and treated. Since fever up to 48 hours following the childhood vaccines would most likely be due to the vaccine rather than an infection, the CHM was sufficiently assured that giving paracetamol within this time period would not significantly increase the risk of a serious infection being missed or pose a risk of toxicity.

The CHM has recommended that the dosage schedule in the paracetamol licences be reviewed in relation to post-vaccination dosage. However, for indications other than post-vaccination fever, parents and carers should be advised to adhere to the manufacturer's dose recommendations and provide a maximum of 2 doses for children aged 2-3 months. 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 delay seeking medical attention.

Public Health England is recommending that parents and carers of infants purchase a supply of infant paracetamol suspension in advance of their infant's first routine childhood immunisations (due from eight weeks) or failing that purchase a supply immediately post immunisation.

Given the disparity between the advice from Public Health England to parents and carers of infants who will be receiving the MenB vaccine and the current GSL licensing of paracetamol, the information in the Patient Information Leaflet and on the packaging of infant paracetamol suspension, it is likely that pharmacists will be asked for advice on the appropriate use of prophylactic paracetamol.

It is important that pharmacists responding to such requests provide appropriate and clear advice, in accordance with that from Public Health England, which supports the recommendations of the JCVI and CHM.

Public Health England has produced a specific leaflet for parents on the use of paracetamol, which will be given to parents at the time of MenB vaccination. In addition to this, there are various PHE leaflets available providing information on the MenB vaccination programme and paracetamol use and a document providing information for healthcare professionals. These can be accessed from: <https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme>

Yours sincerely



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References

JCVI position statement on use of Bexsero® meningococcal B vaccine in the UK

March 2014.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/294245/JCVI_Statement_on_MenB.pdf

Summary of the Commission on Human Medicines meeting held on
Thursday 14 May 2015

https://app.box.com/s/jv487awvqzzsrdql0o34h9gg350ceyd4/1/3477158784/33964483463/1?&_suid=143825356108603759173200760626