



Protecting and improving the nation's health

**Publications Gateway Reference: 2015257**

## Protocol

Supply or administration of paracetamol **oral** suspension 120mg/5mL to infants under 12 months of age receiving primary doses of MenB vaccination

Reference no: *Paracetamol Protocol*  
Version no: *v01.00*  
Valid from: *1 September 2015*  
Review date: *1 March 2016*  
Expiry date: *31 August 2017*

**Public Health England has developed this protocol to facilitate delivery of the National Immunisation Programme.**

This protocol has been prepared by members of the PHE Immunisation Team.

There is no legal requirement for formal authorisation of a protocol. The protocol may be adopted by commissioners and providers to support practitioners in providing the National Immunisation Programme and adhering to their professional standards.

This protocol has been developed to support the provision of a general sales list (GSL) medication, for which a Patient Group Direction is not required.

NMC Standards for Medicines Management require that NMC registrants must only supply and administer medicinal products in accordance with set processes which include a homely remedies protocol. Therefore this protocol is intended to support nurses to practice in accordance with their professional standards when providing GSL paracetamol following Men B vaccination.

**Note: The recommended dosage schedule for paracetamol suspension 120mg/5ml post-MenB vaccination is outside the current paracetamol licence. See Section 4 Off-Label Use for further details.**

## 1. Protocol Development

This protocol has been developed by the following on behalf of Public Health England:

<b>Developed by:</b>	<b>Name</b>
<b>Pharmacist</b>	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head Immunisation, Hepatitis & Blood Safety Department, PHE
<b>Registered Nurse</b>	David Green Nurse Consultant – Immunisations, PHE

## Acknowledgements

<b>Name</b>	<b>Designation</b>
Dr Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Dr Max Kammerling	Screening and Immunisations Lead (SIL) – Surrey and Sussex
Jacqueline Lamberty	Medicines Management Adviser – Public Health England
Gill Marsh	Senior Health Protection Nurse Practitioner, Cheshire & Merseyside Health Protection Team, Public Health England
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire and Lincolnshire
Sue Mulvenna	Pharmacist Lead - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England Lancashire & Greater Manchester / Public Health England.

## 2. Characteristics of Staff

<b>Qualifications and professional registration</b>	This protocol is intended for use by nurses currently registered with the Nursing and Midwifery Council (NMC), providing paracetamol following primary doses of MenB vaccination.
---	---

## 3. Clinical condition or situation to which this protocol applies.

<b>Clinical condition or situation to which this protocol applies</b>	<p>This protocol supports the supply or administration of the first dose of oral paracetamol with MenB vaccination when timely access to a home supply is not available.</p> <p>Paracetamol suspension 120mg/5ml is recommended for the prevention of fever associated with administration of MenB vaccination, Bexsero<sup>®</sup>▼, in accordance with the recommendations given in the <a href="#">MenB bipartite letter</a>.</p>
<b>Criteria for inclusion</b>	<p>Infants who:</p> <ul style="list-style-type: none"> <li>• Are aged from 8 weeks to under 12 months of age</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• Are receiving primary doses of MenB vaccination at the same time as other routine vaccines</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• Do not have timely access to infant paracetamol suspension 120mg/5ml post MenB vaccination.</li> </ul>
<b>Criteria for exclusion<sup>1</sup></b>	<ul style="list-style-type: none"> <li>• Infants for whom no valid consent has been received</li> <li>• Infants under 8 weeks of age</li> <li>• Infants 12 months of age and over</li> <li>• Babies receiving MenB vaccine 12 month booster dose</li> <li>• Preterm infants born at less than 32 weeks gestation and currently weighing less than 4kg – see <b>Action to be taken if the patient is excluded</b> section</li> </ul> <p>In addition infant paracetamol suspension 120mg/5ml should NOT be given to:</p> <ul style="list-style-type: none"> <li>• Infants with a confirmed anaphylactic reaction to a previous dose or to any component of the product;</li> <li>• Infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency</li> <li>• Infants who have taken paracetamol-containing products within the previous 4 hours.</li> <li>• Infants who have already taken four doses of paracetamol-containing product within the current 24 hours</li> </ul>
<b>Cautions including any relevant action to be taken</b>	Should be used with caution in severe renal impairment or severe hepatic impairment – seek advice from infant’s clinician.

<sup>1</sup> Exclusion under this protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit

<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from a person legally able to act on the infant's behalf, must be obtained before administration.</p> <p>Advise parent/carer about the potential for a post immunisation fever and how to manage this – see Patient Advice / Follow-up below.</p> <p>Document advice given.</p>
<p><b>Action to be taken if the patient is excluded</b></p>	<p>Seek appropriate advice from the infant's clinician/GP as appropriate.</p> <p>Paracetamol is not indicated prophylactically with MenB vaccine doses given from 12 months of age. Parents can be advised to treat any fever that may develop in accordance with the standard paracetamol dosing recommendations for the child's age.</p> <p>Preterm infants born less than 32 weeks gestation and currently weighing less than 4kg are recommended three prophylactic doses of paracetamol post MenB vaccination but should have paracetamol prescribed for them with a dose appropriate to the infant's weight at the time of vaccination, in accordance with the oral dose recommendation for their age in the cBNF.</p> <p>Infants with allergies or otherwise unable to receive paracetamol suspension - refer to patient's clinician as an alternative paracetamol product may be appropriate.</p> <p>Infants who have already taken paracetamol should be advised to allow a minimum of 4 hours between doses and administer no more than 4 doses in any 24 hour period.</p> <p>Document reason for exclusion and any action taken in infant's clinical records.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>

#### 4. Description of Treatment

<b>Name, strength &amp; formulation of drug</b>	Paracetamol oral suspension 120mg/5ml
<b>Legal category</b>	General Sales List (GSL)
<b>Black Triangle▼</b>	No.
<b>Off-label use</b>	<p>Yes:</p> <p>This protocol advocates prophylactic use of paracetamol post Men B immunisation. It advises three 2.5ml (60mg) prophylactic doses are provided to infants post MenB vaccination and advises that infants developing a fever may be treated with paracetamol for up to 48 hours post immunisation.</p> <p>Paracetamol licences at the time of writing cover the treatment of pain and fever, not prophylaxis, and state that no more than two 60mg doses of paracetamol should be given to infants aged 2 to 3 months, without seeking the advice of a doctor or pharmacist.</p> <p>The Commission on Human Medicines (CHM) (May 2015), who advise ministers on the safety, efficacy and quality of medicinal products, has reviewed PHE recommendations for prophylactic paracetamol doses following MenB vaccination with Bexsero<sup>®</sup>▼, as advised by the JCVI, and supports the recommendations. See below:</p> <p><i>The Commission noted that the licences for infant paracetamol suspension currently state that no more than two doses of paracetamol should be given to children aged 2 to 3 months, without seeking the advice of a doctor or pharmacist. This limit was to ensure that fever which may be due to a serious infection in young infants is quickly diagnosed and treated.</i></p> <p><i>The Commission fully supported the JCVI recommendation to help reduce the risk of fever following vaccination with the meningitis B vaccine. Since fever up to 48 hours following the childhood vaccines would most likely be due to the vaccine rather than infection, the Commission 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 Commission also recommended that the dosage schedule in the paracetamol licences be reviewed in relation to post-vaccination dosage.</i></p> <p>Note: The recommendation to use paracetamol described above relates only to its use following MenB vaccine when MenB vaccine is administered at the same time as other primary immunisations to infants under 12 months of age. In all other circumstances the manufacturer's instructions should be followed. For non-vaccine related fever the limit of two doses of paracetamol to children aged 2 to 3 months remains to ensure that fever which may be due to a serious infection in young infants is quickly diagnosed and treated.</p>
<b>Route / method of administration</b>	Oral administration Massage contents of sachet before opening

<b>Dose and frequency of administration</b>	<p><b>2.5ml (60mg) dose</b> (half a sachet) to be measured using an appropriately sized measuring spoon or oral syringe, to be administered during the immunisation appointment or as soon as possible following immunisation with MenB vaccine, Bexsero<sup>®</sup>▼.</p> <p>Parents should be advised to provide two further preventative doses of 2.5ml (60mg) paracetamol suspension 120mg/5ml to be administered at home, 4-6 hours after the preceding dose – these doses are not provided by the GP practice, see follow-up advice.</p>
<b>Duration of treatment</b>	<p>Single dose to be supplied or administered following MenB vaccination.</p> <p>Parents to be advised regarding administration of further doses in accordance with PHE recommendations and the need to purchase a home supply of paracetamol 120mg/5ml suspension.</p>
<b>Quantity to be supplied / administered</b>	<p>2.5ml (60mg) dose of paracetamol suspension 120mg/5ml to be administered</p> <p>OR</p> <p>1 x 5ml sachet of paracetamol suspension 120mg/5ml to be supplied to the parent/carer, with an appropriately sized measuring spoon or oral syringe, to be given to the infant, by the parent/carer, as soon as possible after vaccination. Parents/carer to be advised to administer to the infant 2.5ml (60mg), which is half the sachet, to be measured using an appropriately sized measuring spoon or oral syringe, and then discard the sachet and its remaining contents.</p>
<b>Supplies</b>	<p>Centrally purchased paracetamol sachets for the national immunisation programme for the NHS can be ordered via ImmForm. This provision of paracetamol is only for the first paracetamol dose post MenB immunisation, when parents/carers don't have ready access to a purchased supply of paracetamol suspension 120mg/5ml.</p> <p>Parents/carers will be required to purchase a supply of paracetamol infant suspension 120mg/5ml (any brand or presentation ie botte) for subsequent doses and future immunisations.</p> <p>Centrally purchased paracetamol is available for the initial launch of the MenB programme whilst the need for paracetamol is embedded into public health messages leading up to infant primary immunisation appointments and whilst manufacturers have time to respond to the change in recommendations regarding the use of paracetamol following routine immunisations.</p> <p>Provision of centrally purchased paracetamol is not currently planned to extend beyond April 2016 at which point parents/carers will be expected to purchase paracetamol suspension 120mg/5ml in advance of their infant's immunisation appointment to provide fever prophylaxis and management.</p>
<b>Storage</b>	<p>Do not store above +25°C.</p> <p>Store in original packaging in order to protect from light.</p>
<b>Disposal</b>	<p>No special requirements.</p> <p>The sachet and its remaining contents should be discarded after administering a dose and not retained for future doses.</p>

<b>Drug Interactions<sup>2</sup></b>	<p>The clinical significance of any drug interactions in relation to the short term use of paracetamol indicated in this protocol is likely to be minimal and does not contraindicate paracetamol use.</p> <p>Avoid concomitant use of other paracetamol-containing products.</p>
<b>Identification &amp; Management of Adverse Reactions<sup>2</sup></b>	<p>Adverse effects of paracetamol are rare but hypersensitivity/anaphylactic reactions including skin rash may occur. Very rare cases of serious skin reactions have been reported.</p> <p>Patients should be informed about the signs of serious skin reactions, and use of the paracetamol should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.</p> <p>A detailed list of adverse reactions associated with paracetamol suspension 120mg/5ml is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Reporting procedure of Adverse Reactions</b>	<p>Healthcare professionals and parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>Any adverse reaction should be documented in the infant's record and the infant's GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Supply PHE leaflet <a href="#">Using paracetamol to prevent and treat fever after MenB vaccination</a>.</p> <p>The manufacturer's patient information leaflet (PIL) should be available for parents/carers to read on request – see <b>Patient Advice</b> section.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">3-minute guide: Protecting your baby against meningitis and septicaemia caused by meningococcal B bacteria. Information about the MenB vaccine and paracetamol use</a></li> <li>• <a href="#">Protecting your baby against meningitis and septicaemia caused by meningococcal B bacteria. Information about the MenB vaccine and paracetamol use</a></li> </ul> <p>Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></p>
<b>Patient advice / Follow up treatment</b>  (continued over page)	<p>Advise parent/carer to purchase a home supply of paracetamol 120mg/5ml suspension (this can be any brand or presentation ie a bottle).</p> <p>Advise parent/carer that the dosing advice on the purchased product and manufacturer's patient information leaflet will differ from the dosing advice recommended post MenB vaccination.</p> <p>Advise parent/carer when the subsequent dose is due:</p> <ul style="list-style-type: none"> <li>• A second dose of 2.5ml (60mg) paracetamol suspension 120mg/5ml should be administered 4-6 hours after the initial dose.</li> <li>• A third dose of 2.5ml (60mg) paracetamol suspension 120mg/5ml should be administered 4-6 hours after the second dose.</li> </ul> <p>After the third paracetamol dose some babies may still develop a</p>

<sup>2</sup> Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

<p><b>Patient advice / Follow up treatment</b> (continued)</p>	<p>fever or continue to be febrile. Fever in the 48 hours after vaccination can be managed with paracetamol at home if the infant is otherwise well.</p> <p>If the infant remains febrile 48 hours after immunisation medical advice should be sought to exclude other causes.</p> <p>If a fever develops parents/carers should keep the infant cool by making sure they don't have too many layers of clothes or blankets, and give them lots of fluids. If the baby is breast-fed, the best fluid to give is breast milk.</p> <p>Paracetamol may mask a fever due to other underlying causes such as systemic bacterial infection. Therefore parents/carers should not delay in seeking medical advice if they are concerned that their infant is otherwise unwell.</p> <p>Parents should be advised that these dosing recommendations are specific to paracetamol use in the 48 hours post MenB vaccination and the manufacturers dosage instructions should be followed at all other times.</p> <ul style="list-style-type: none"> <li>• Do not give more than 4 doses in any 24 hour period.</li> <li>• Leave at least 4 hours between doses.</li> <li>• Do not give anything else containing paracetamol while giving this medicine.</li> <li>• The parent/carer should be advised to seek medical advice in the event of an adverse reaction.</li> </ul>
<p><b>Special Considerations / Additional Information</b></p>	<p>The paracetamol recommendations following Men B vaccination differ from the dosing information post-immunisation on the product packaging and literature. Parents should be made aware of this discrepancy. Following primary doses of Men B vaccination parents and carers should be given the PHE paracetamol leaflet "<a href="#">Using paracetamol to prevent and treat fever after MenB vaccination</a>" and advised to follow the specific dosing recommendations following MenB vaccination.</p> <p>If paracetamol is administered or supplied the manufacturer's patient information leaflet should be made available to any parent/carer who requests it. A manufacturer's patient information leaflet will be available in each box of 12 sachets or can be accessed from <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<p><b>Records</b></p>	<p>Document in the patient record if paracetamol was supplied or administered in accordance with this protocol.</p> <p>All records should be clear, legible and contemporaneous.</p>

## 6. Key References

<b>Key references</b>	<ul style="list-style-type: none"><li>• Calpol<sup>®</sup> Summary of Product Characteristics. McNeil Products Limited. Updated 25 Nov 2014 <a href="http://www.medicines.org.uk/emc/medicine/20237">http://www.medicines.org.uk/emc/medicine/20237</a></li><li>• Summary of the Commission on Human Medicines meeting held on Thursday 14 May 2015 <a href="https://app.box.com/s/jv487awvqzsrdbl0o34h9gg350ceyd4/1/3477158784?&amp;_suid=143533547092908375073023549922#/s/jv487awvqzsrdbl0o34h9gg350ceyd4/1/3477158784/33964483463/1?&amp;_suid=143825356108603759173200760626">https://app.box.com/s/jv487awvqzsrdbl0o34h9gg350ceyd4/1/3477158784?&amp;_suid=143533547092908375073023549922#/s/jv487awvqzsrdbl0o34h9gg350ceyd4/1/3477158784/33964483463/1?&amp;_suid=143825356108603759173200760626</a></li><li>• Immunisation Against Infectious Disease: The Green Book, Chapter 22. Updated 28 July 2015 <a href="https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22">https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22</a></li><li>• Meningococcal B (MenB) vaccination programme. Published 30 June 15. <a href="https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme">https://www.gov.uk/government/collections/meningococcal-b-menb-vaccination-programme</a></li><li>• Bipartite Letter: Introduction of MenB vaccination for infants. Published 22 June 2015. <a href="https://www.gov.uk/government/publications/menb-vaccination-introduction-from-1-september-2015">https://www.gov.uk/government/publications/menb-vaccination-introduction-from-1-september-2015</a></li><li>• Leaflet: Using paracetamol to prevent and treat fever after MenB vaccination <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/450890/9413-paracetamol-menB-2page-A4-05-web.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/450890/9413-paracetamol-menB-2page-A4-05-web.pdf</a></li><li>• PHE Immunisation Collection. Updated 9 December 2014 <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• British National Formulary (BNF) and British National Formulary for Children (BNF-C) <a href="http://www.BNF.org">www.BNF.org</a> <a href="https://www.evidence.nhs.uk/formulary/bnfc/current/4-central-nervous-system/47-analgesics/471-non-opioid-analgesics-and-compound-analgesic-preparations/paracetamol">https://www.evidence.nhs.uk/formulary/bnfc/current/4-central-nervous-system/47-analgesics/471-non-opioid-analgesics-and-compound-analgesic-preparations/paracetamol</a></li><li>• Nursing &amp; Midwifery Council (NMC) Standards for Medicines Management. Published April 2010 <a href="http://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/">http://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/</a></li></ul>
-----------------------	--