

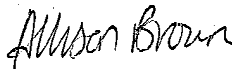



**NHS AYRSHIRE & ARRAN**  
**PATIENT GROUP DIRECTION**

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| <b>Name of Medicine :</b>     | Paracetamol Suspension 120mg/5mls        |
| <b>Legal Classification :</b> | Pharmacy (P) or General Sales List (GSL) |
| <b>PGD Ref No :</b>           | CP 24 277                                |
| <b>Replacing PGD Ref No :</b> | CP 22 277                                |

|                         |                                |
|-------------------------|--------------------------------|
| <b>Effective Date :</b> | 21 <sup>st</sup> November 2024 |
| <b>Review Date :</b>    | 20 <sup>th</sup> November 2026 |

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| <b>Professional Group authorised to use PGD on completion and submission of an Approved Practitioner Form:</b> | Community Pharmacists registered as a member of the General Pharmaceutical Council<br><br>NB For Nurses ADMINISTERING paracetamol at vaccination appointments see PGD HBN 24 325 |
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| PGD prepared/reviewed* by :<br>(*delete as appropriate) |   |  |   |
|---|---|--|---|
|   | Doctor  | Pharmacist   | Nurse   |
| <b>Name</b>   | John Freestone  | Iain Fulton  | Allison Brown   |
| <b>Signature</b>  |  |  |  |
| <b>Date</b>   | 02/10/2024  | 02/10/2024   | 02/10/2024  |

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| <b>Approved on behalf of NHS Ayrshire &amp; Arran</b>   |
| <b>Chair or vice chair PGD group:</b>   |
| <b>Name: Jen Pennycook</b>  |
| <b>Signature:</b>  |
| <b>Date: 21/11/2024</b>   |

| Description of Treatment               |   |
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| Name of medicine : Paracetamol         |   |
| POM/P/GSL :                            | P or GSL  |
| Pharmaceutical Form :                  | Suspension  |
| Strength :                             | 120mg/5mls  |
| Clinical situation for use of this PGD | Prophylaxis of post vaccination fever   |
| Inclusion criteria                     | <p>Infants under 12 months of age who are receiving primary doses of MenB vaccine at the same time as other routine vaccines.</p> <p>Men B vaccine will usually be given with other routine childhood immunisation at age 2 and 4 months.</p> <p><b>Most infants will be greater than two months of age when presenting for first dose however a small number may be under 8 weeks old. These children are included.</b></p>  |
| Exclusion criteria                     | <p>Infants:</p> <ul style="list-style-type: none"> <li>• 12 months of age or over.</li> <li>• Receiving MenB vaccine at 12 month booster dose.</li> <li>• Infants born at &lt;32 weeks and currently weighing less than 4kg.</li> <li>• Known to have hypersensitivity to paracetamol or any ingredient in the product. Check the marketing authorisation holder's summary of product characteristics (SPC) for details of a brand's ingredients.</li> <li>• Known to have impaired liver or kidney function.</li> <li>• Known to have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency.</li> </ul> <p>If administering paracetamol:</p> <ul style="list-style-type: none"> <li>• Known to have taken a paracetamol based analgesic within the previous 4 hours.</li> <li>• Known to have taken the maximum recommended daily dose of paracetamol within the previous 24 hours.</li> <li>• Non-consent.</li> </ul> |

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| Dosage :  | <p>60mg (2.5ml of 120mg/5ml oral suspension).</p> <p>Three doses of paracetamol are required: A first dose of 60mg (2.5ml of 120mg/5ml) as soon as possible after vaccination with Men B vaccine.</p> <p>A second 60mg (2.5ml of 120mg/5ml oral suspension) dose after 4-6 hours.</p> <p>A third 60mg (2.5ml of 120mg/5ml oral suspension) dose after a further 4-6 hours.</p> <p>Further doses at intervals appropriate to the age of the child may be administered in the period of up to 48 hours post vaccination if pyrexia persists.</p> <p>N.B. For non-vaccine related fever the limit of two doses of paracetamol to children 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> |
| Total Dosage:   | 180mg in 24 hours  |
| Route of Administration :                                   | <i>Oral</i>  |
| Frequency of Administration :                               | 4 -6 hourly  |
| Duration of Treatment :                                     | 3 doses over 24 hours initially up to 6 doses over 48 hours.   |
| Total Treatment Quantity :                                  | 180mg (7.5ml) in 24 hours<br>360mg (15ml) in 48 hours  |
| Action if patient is excluded from treatment under this PGD | Advise about risk of fever following vaccination and how to manage this-see patient advice section.<br>Refer to GP.  |
| Interactions  | Refer to SPC or online BNF.  |
| Adverse Effects   | <p>In the event of severe adverse reaction the parent/carer of the child should be advised to seek medical advice.</p> <p>Adverse effects of paracetamol are rare but hypersensitivity or anaphylactic reactions including skin rash may occur. Very rare cases of serious skin reactions have been reported.</p> <p>The parent or carer of the child should be informed about the signs of serious skin</p>   |

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|  | <p>reactions, and use of the paracetamol should be discontinued at the first appearance of skin rash or any other signs of hypersensitivity.</p> <p>Use the Yellow Card system to report adverse drug reactions online at <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a>.</p>   |
| Follow-up treatment                                | Contact GP if fever persists as in Advice to patient/carer.  |
| Written/Verbal Advice to be given to patient/carer | <p>Explain treatment and course of action:</p> <p>The Green Book advises that after the third paracetamol dose some babies may still develop a 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 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>If the infant remains febrile 48 hours after immunization medical advice should be sought to exclude other causes.</p> <p>Paracetamol may mask a fever due to other underlying causes such as systemic bacterial infection. Parents/carers should not delay in seeking medical advice if they are concerned that their infant is otherwise unwell.</p> <p>Parents/carers should be advised that these dosing recommendations are specific to paracetamol use in 48 hours post Men B vaccination and the manufactures 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 (3 doses for infants 1 to 3 months).</li> <li>• Leave at least 4 hours between doses.</li> <li>• Do not give anything else containing paracetamol while giving this medicine.</li> </ul> |

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|  | <ul style="list-style-type: none"> <li>• The parent/carer should be advised to seek medical advice in the event of an adverse reaction.</li> </ul> <p>Pharmacists should advise that:</p> <ul style="list-style-type: none"> <li>• If the infant has received paracetamol containing products within the last four hours before attending for vaccination then they should wait 4-6 hours before administering further doses.</li> <li>• The dosing advice on the purchased product and the manufacturers patient information leaflet will differ from the dosing advice recommended post MenB vaccination.</li> </ul> <p>Give parent/carer a copy of the relevant patient information leaflet, if appropriate.</p> |
| Record required of Supply/Administration | <p>The following information should be recorded in the PMR</p> <ul style="list-style-type: none"> <li>• Name of preparation</li> <li>• Quantity</li> <li>• Any directions for use</li> <li>• Date of supply</li> </ul>  |