Paracetamol 120mg/5ml Suspension for prophylaxis of post vaccination fever

GG&C PGD ref no: 2024/2689

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Version History

Version	Date	Summary of Changes
5	31/3/21	Current document
6	17/8/22	Amendment of Inclusions to reflect Public Health Scotland leaflet and BNF advice regarding infants born <32 weeks and weighing <4kg.
7	07/05/2024	Paracetamol appendix updated for clarity

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Clinical Condition	
Indication:	Prevention of post immunisation fever following administration of meningococcal group B conjugate (MenB) vaccine (Bexsero®)
Inclusion criteria:	Infants under 12 months of age who are receiving primary doses of MenB vaccine at the same time as other routine vaccines. MenB vaccine will usually be given with other routine childhood immunisation at age 2, 4 months and 12 months. **Most infants will be greater than two months of age when presenting for first dose but a small number may be under 8 weeks old. These children are included.**
Exclusion criteria:	Infants: • 12 months of age or over • Receiving MenB vaccine at 12 month booster dose • Infants born at <32 weeks and currently weighing less than 4kg • 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 particular brand's ingredients. • Known to have impaired liver or kidney function • Known to have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency If **administering** paracetamol: • Known to have taken a paracetamol based analgesic within the previous 4 hours. • Known to have taken the maximum recommended daily dose of paracetamol within the previous 24 hours. • Non-consent

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Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:	If a very premature baby (born at <32 weeks) and currently weighing less than 4kg presents for supply of prophylactic paracetamol in primary care. Refer to GP This reflects dosing advice in the BNFc (https://bnfc.nice.org.uk/drugs/paracetamol/) and Public Health Scotland leaflet 'What to expect after immunisation' http://www.healthscotland.com/documents/6122.aspx Appendix 1. Offers advice on recommended paracetamol doses for infants born <32 weeks weighing <4kg when presenting for vaccination. It has been prepared in consultation with NHSGGC Paediatric Specialist Pharmacists. Some parents/carers may administer a dose of paracetamol to an infant before attending a clinic. Pharmacists should advise parent/carers to tell the healthcare professional running the immunisation clinic that they have done this and when. Nursing Practitioners running immunisation clinics should check whether a dose of paracetamol has already been given by a parent/carer. Some brands of paracetamol suspension contain liquid sorbitol and maltitol which means that they are unsuitable for those individuals known to have an inherited intolerance to fructose.
Action if patient declines or is excluded:	Advise about the risk of fever following vaccination with Bexsero® and how to manage this – see patient advice section. Refer to GP.
Referral arrangements for further advice / cautions:	Both community pharmacists (supplying paracetamol) and nursing practitioners (administering and supplying paracetamol within the immunisation clinic) should refer the infant to their GP when there is any uncertainty over their suitability to be given paracetamol.

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Drug Details	
Name, form & strength of medicine:	Paracetamol Oral suspension 120mg in 5ml (sugar free)
Route/Method of administration:	Oral
Dosage (include maximum dose if appropriate):	60mg (2.5ml of 120mg/5ml oral suspension) Three doses of paracetamol are required: 60mg (2.5ml of 120mg/5ml) as soon as possible after vaccination with Men B vaccine. A second 60mg dose after 4-6 hours. A third 60mg dose after a further 4-6 hours. 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 N.B. 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.
Frequency:	Pharmacy - 4-6 hourly Immunisation clinic - single dose
Duration of treatment:	3 doses over 24 hours initially.
Maximum or minimum treatment period:	48 hours
Quantity to supply/administer:	Supply - 100mls Administer 2.5ml
Supply, Administer or Both:	Pharmacy - Supply only Immunisation clinic - Administer only
▼Additional Monitoring:*	No

*** The black triangle symbol has now been replaced by European "additional monitoring" (▼)**

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Legal Category:	P or GSL
Is the use outwith the SPC:**	Yes The licensed indication for prophylaxis of post immunisation fever following vaccination with Bexsero® at 2, 3 and 4 months, states infants from 2 months of age. Most infants will be greater than two months of age when presenting for first dose but a small number may be under 8 weeks old. These children are included as per recommendation in the CMO letter http://www.sehd.scot.nhs.uk/cmo/CMO(2015)17.pdf
Storage requirements:	Store at ambient room temperature (under 25C)
Warnings including possible adverse reactions and management of these:	For full details/information on possible side effects, refer to the marketing authorisation holder's SPC or current BNF for children: In the event of severe adverse reaction individual should be advised to seek medical advice. 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. 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. Use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/

**** Summary of Product Characteristics**

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Advice to patient/carer including written information provided:	Explain treatment and course of action: 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. 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. If the infant remains febrile 48 hours after immunisation medical advice should be sought to exclude other causes. 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. 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. • Do not give more than 4 doses in any 24 hour period (3 doses for infants 1 to 3 months) • Leave at least 4 hours between doses. • Do not give anything else containing paracetamol while giving this medicine. • The parent/carer should be advised to seek medical advice in the event of an adverse reaction. Pharmacists should advise that: • 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. • The dosing advice on the purchased product and manufacturer's patient information leaflet will differ from the dosing advice recommended post MenB vaccination. Give patient a copy of relevant patient information leaflet, if appropriate.
Monitoring (if applicable):	n/a
Follow up:	Contact GP if fever persists as in Advice to Patient/Carer

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Staff Characteristics	
Professional qualifications:	Those registered healthcare professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.
Specialist competencies or qualifications:	Has undertaken appropriate training to carry out clinical assessment of patient leading to assessment that requires treatment according to the indications listed in this PGD. Has undertaken appropriate training for working under PGDs for the supply and administration of medicines. To have appropriate indemnity insurance arrangements in place.
Continuing education & training:	The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development.

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Referral Arrangements and Audit Trail	
Referral arrangements	GP if required
Records/audit trail:	**For Pharmacy** Patient's name, address, date of birth Date supplied and name of pharmacist who supplied the medication Advice given to patient's parent or carer **For Immunisation clinic** Patient's name, address, date of birth and consent given Contact details of GP (if registered) Diagnosis Dose, form administered and batch details Advice given to patient (including side effects) Signature/name of staff who administered or supplied the medication Details of any adverse drug reaction and actions taken including documentation in the patient's medical record Referral arrangements including self-care
References/Resources and comments:	Marketing authorisation holder's Summary of Product Characteristics http://www.medicines.org.uk/emc/ BNFc – British National Formulary www.medicinescomplete.com Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Immunisation against Infectious Disease [Green Book] chapter 22 Meningococcal https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22 All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) http://www.sehd.scot.nhs.uk/index.asp?category=9&name=&org=%25 'What to expect after immunisation leaflet; Babies and children up to 5 years old' http://www.healthscotland.com/documents/6122.aspx

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This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use.
The original signed copy will be held at Pharmacy Services, Clarkston Court, 56 Busby Road, Glasgow.
The PGD must be easily accessible in the clinical setting.

Organisation:	**NHS Greater Glasgow & Clyde**

Professionals drawing up PGD/Authors

	Designation and Contact Details
*Name: Sarah Marshall Signature: Date: **22/05/2024**	Designation: Specialist Public Health Pharmacist E-mail address: sarah.marshall4@ggc.scot.nhs.uk
Name: Dr Iain Kennedy Signature: Date: **22/05/2024**	Designation: Consultant in Public Health Medicine E-mail address: iain.kennedy@ggc.scot.nhs.uk
Name: Tina McMichael Signature: Date: **22/05/2024**	Designation: Lead Health Protection Nurse Specialist E-mail address: tina.mcmichael@ggc.scot.nhs.uk
Name: Maria Tracey Signature: Date: **22/05/2024**	Designation: Clinical Pharmacist, Women and Children E-mail address: maria.tracey@ggc.scot.nhs.uk

*** Lead Author**

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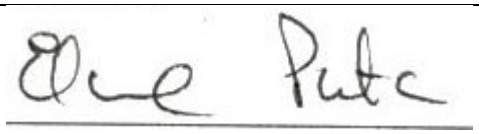
AUTHORISATION:

NHSGG&C PGD Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		**22/05/2024**

NHSGG&C PGD Sub-Committee of ADTC		
Interim Chief Nurse, North Sector, NHS GGC in BLOCK CAPITALS	**Signature:**	**Date:**
Kevin McAuley		**22/05/2024**

Pharmacist representative of PGD Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		**22/05/2024**

Antimicrobial use

If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.

Microbiology approval	Name:	Designation:
	Signature:	Date:
	(on behalf of NHS GG&C AMT)	

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Local Authorisation:

Service Area for which PGD is applicable:	Community Pharmacy		
Record/Audit Trail	There must be appropriate records kept and maintained by the pharmacist to enable verification of service provision and training requirements, and provide information for internal and external audit and evaluation purposes.		
Nominated individual who agrees to keep list of practitioners operating under the PGD current and up to date (Lead Professional):			
Name:	**Signature:**	**Designation:**	**Date:**
Alan Harrison Email contact address: alan.harrison@ggc.scot.nhs.uk		Lead Pharmacist Community Care	30/05/2024

PGDs do not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.

Name of Pharmacist		**GPhC No**	

I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to provide these medicines only in accordance with this PGD.

Sign:		*Date:*

ONCE YOU HAVE SIGNED THE PGD, YOU ***MUST*** COMPLETE THE ELECTRONIC FORM (LINK BELOW)

PGDs - Greater Glasgow and Clyde (office.com)

NHS Greater Glasgow & Clyde Patient Group Direction (PGD) for Health Care Professionals	

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Patient Group Direction Audit Form
Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

Name and post of Designated Lead person within each practice/clinic base:		
Location/Clinic Base:	**Date of audit:**	
Tick as appropriate. If 'no', state action required	**Y**	**N Action**
Is the PGD or PGDs utilised within the clinical area?		
Has the PGD or PGDs been reviewed within the 2 year limit?		
Do the managers listed on the PGD or PGDs hold a current list of authorised staff?		
Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?		
Do all staff meet the training requirements identified within the PGD?		
Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?		
Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?		
Where the medicine requires refrigeration. (Delete if not required).		
Is there a designated person responsible for ensuring that the cold chain is maintained?		
Is there a record that the fridge temperature has been monitored to required levels?		
If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response).		

Name:	Date of audit:

Keep copies of completed audits alongside your PGD for local reference.
Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.