

**PROPHYLACTIC PARACETAMOL PROVISION
FOR THE PREVENTION AND TREATMENT OF FEVER
POST IMMUNISATION AGAINST MENINGOCOCCAL GROUP B DISEASE**

Background

1. Immunisation against meningococcal serogroup B disease (MenB) has been 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 guidance provides advice for pharmacists to help them understand the requirement for use of paracetamol with the MenB vaccine and the Scottish arrangements around its provision.

Situation

2. 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.
3. Given that fever has been a common adverse reaction in trials of Bexsero®, the Joint Committee on Vaccination and Immunisation (JCVI) has recommended that paracetamol should be given **prophylactically** when Bexsero® is given with the routine vaccines in infants under one year of age.
4. Three 2.5ml doses of infant paracetamol suspension 120mg/5mL should be given orally, with the first dose provided at the same time as or as soon as possible after vaccination, and two subsequent doses at intervals of four to six hours.

Assessment

5. In Scotland it has been agreed that community pharmacists will provide a supply of infant paracetamol oral suspension 120mg/5ml for the prevention of post vaccination fever childhood MenB vaccination as a new component of the Public Health Service.
6. The supply will be available to any infant under **one year of age** in advance of or after receiving Bexsero® vaccine.
7. The updated advice that three 2.5ml doses of infant paracetamol suspension 120mg/5ml should be given prophylactically is a change to previous advice where the prophylactic use of paracetamol has not been routinely recommended following immunisation.
8. In addition when given to infants of 2 months, the recommended dose regimen of paracetamol of three doses exceeds the current post-immunisation licensing restriction on Pharmacy (P) and General Sales List (GSL) paracetamol products, which advise a *maximum* of two doses.

9. 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 vaccine up to 48 hours following immunisation to manage post-immunisation fever in those aged two months old.
10. 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.**
11. The CHM has recommended that the Patient Information Leaflets (PILs) in infant paracetamol oral suspension products should be updated to reflect the JCVI advice in due course.
12. Given the current 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 and other healthcare professionals will be asked for advice on the appropriate use of prophylactic paracetamol. **It is important therefore that responses to such requests provide the correct, appropriate, clear and updated advice.**

Recommendations and Advice

13. Before or after infants have been vaccinated with the Bexsero® vaccine, their parents/representatives/guardians will be advised to attend their local community pharmacy where they will be provided with a supply of infant paracetamol oral suspension 120mg/5ml and a 2.5ml syringe.
14. They should, wherever possible, provide confirmation of MenB vaccination **by presenting the infant's 'Personal Child Health Record' booklet.**
15. Pharmacists should advise parents to give a **2.5ml dose** to the child **at the same time as or as soon as is possible** after the vaccine is administered, and to give **two further doses at 4-6 hourly intervals.**
16. 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.**
17. The national Patient Group Direction (PGD) for the prophylactic provision of infant paracetamol suspension will be used to underpin the supply until the advice on corresponding SPCs and PILs for the products have been updated.
18. It should be noted that the national PGD is not intended to replace GP prescribing (or supply) of prophylactic paracetamol, but to support the overall smooth running of the MenB programme. Both arrangements will remain in place to provide flexibility of delivery, for example in remote and rural areas where the community pharmacy option may not be available.
19. Further details regarding the introduction of MenB immunisation for infants are available at Scottish Health on the Web: [http://www.sehd.scot.nhs.uk/cmo/CMO\(2015\)11.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2015)11.pdf)

PUBLIC HEALTH SERVICE

Patient Service element of Public Health Service (Support for Meningitis B vaccination programme)

**MENINGOCOCCAL GROUP B (MENB) VACCINATION PROGRAMME:
PROVISION OF PROPHYLACTIC PARACETAMOL SUSPENSION FOR THE
PREVENTION OF POST IMMUNISATION FEVER****SERVICE SPECIFICATION****1. Service aim**

- 1.1 To provide, where clinically indicated, a free supply of infant paracetamol oral suspension 120mg/5mL for prophylactic pyrexia relief in advance of or following childhood Meningococcal Group B (MenB) vaccination.

2. Service outline and standards

- 2.1 The supply of infant paracetamol suspension 120mg/5mL for prophylactic pyrexia is available to any infant under one year of age scheduled to receive or after receiving Bexsero[®] Men B vaccine.
- 2.2 Initially the supply will be underpinned by the Patient Group Direction (PGD) for the prophylactic provision of infant paracetamol suspension until the Patient Information Leaflet (PIL) has been updated.
- 2.3 Before or post vaccination the parent/patient representative/guardian will present at the community pharmacy and, wherever possible, provide confirmation of MenB vaccination **by presenting the infant's 'Personal Child Health Record' booklet.**
- 2.4 The pharmacist provides a supply of infant paracetamol suspension 120mg/5mL according to the PGD and a 2.5ml oral syringe. The product should be labelled with the following instructions:
 - i. **Give a 2.5ml dose orally at the same time as, or as soon as possible after vaccination,**
 - ii. **a second 2.5ml dose four to six hours after the first dose, and**
 - iii. **a third 2.5ml dose after a further four to six hours.**
- 2.5 The pharmacist records the supply on a CPUS form following the procedure set out in section 3.
- 2.6 The pharmacist maintains a record for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. **Wherever possible the infant should be identified using their CHI number.**
- 2.7 The pharmacist ensures that the parent/patient representative/guardian is counselled appropriately **including the updated advice on the use of prophylactic paracetamol and any possible initial discrepancy between information in the Patient Information Leaflet (PIL) or on the packaging of infant paracetamol suspension products.**

2.8 The service is provided according to any required regulatory and professional standards.

3. Service Procedure

3.1 The pharmacist follows the procedure detailed below:

Step 1	The pharmacist consults with the parent/representative/guardian and, wherever possible, provides confirmation of MenB vaccination by presenting the infant's 'Personal Child Health Record' booklet.
Step 2	<p>The pharmacist provides a supply of infant paracetamol suspension 120mg/5mL according to the PGD and a 2.5ml oral syringe.</p> <p>The supply is recorded in the infant's patient medication record (PMR) and the product is labelled with the following instructions:</p> <ul style="list-style-type: none"> (i) Give a 2.5ml dose orally at the same time as or as soon as possible after vaccination, (ii) a second 2.5ml dose four to six hours after the first dose, and (iii) a third 2.5ml dose after a further four to six hours.
Step 3	<p>The supply is recorded on a CPUS form and an endorsement of MVP included before the product name. For example:</p> <p style="text-align: center;">“MVP infant paracetamol suspension S/F 120mg/5mL”</p>
Step 4	The pharmacist counsels the parent/patient representative/guardian appropriately including the updated advice on the use of prophylactic paracetamol and any possible initial discrepancy between information in the Patient Information Leaflet (PIL) or on the packaging of infant paracetamol suspension products.
Step 5	The CPUS form is submitted to PSD as usual.
Step 6	The pharmacy contractor receives reimbursement for the infant paracetamol suspension supply using the Part 7 Drug Tariff price as per normal payment processes.
Step 7	The pharmacy contractor receives payment for remuneration for the service (based on the MVP endorsement) as per normal payment processes.
Step 8	<p>In the case of an actual or suspected adverse drug reaction the pharmacist will consider whether there is a requirement to report the reaction to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card reporting mechanism.</p> <p>All employed pharmacists, pharmacy technicians and locums should undertake, with certificate of completion, the six interactive e-learning modules on ADRs developed by NES and the Yellow Card Centre Scotland. Section 1, Annex A of PCA (P) (2015) 26</p>



**NATIONAL PATIENT GROUP DIRECTION FOR SUPPLY OF
PARACETAMOL ORAL SUSPENSION 120 mg/5ml FOR PREVENTION
OF POST IMMUNISATION FEVER FOLLOWING ADMINISTRATION OF
MENINGOCOCCAL GROUP B VACCINE (BEXSERO®) BY AUTHORISED
COMMUNITY PHARMACISTS WORKING IN SCOTLAND**

**IT IS THE RESPONSIBILITY OF THE INDIVIDUAL TO ENSURE THEY ARE USING THE MOST UP TO
DATE PGD**

Authorisation

Developed on behalf of NHS Scotland by NHS National Services Scotland (Health Protection Scotland) by:

Physician Dr Syed Ahmed Signature Dr Syed Ahmed

Pharmacist Mr William Malcolm Signature Mr William Malcolm

Authorised for use on behalf of NHS Lothian by

Medical Director Dr D Farquharson Signature Dr D Farquharson

Senior Pharmacist Aileen Muir Signature Aileen Muir

Clinical Governance Lead Dr D Farquharson Signature Dr D Farquharson

Date Approved 09/10/2015

Effective From 09/10/2015 Expires 01/10/2017

**PATIENT GROUP DIRECTION FOR SUPPLY OF
PARACETAMOL ORAL SUSPENSION 120mg/5ml FOR
PREVENTION OF POST IMMUNISATION FEVER FOLLOWING
ADMINISTRATION OF MENINGOCOCCAL GROUP B VACCINE
(BEXSERO®) BY AUTHORISED COMMUNITY PHARMACISTS
WORKING IN SCOTLAND**

(Approved September 2015 - Review Date October 2017)

GENERAL POLICY
PATIENT GROUP DIRECTION FOR SUPPLY OF PARACETAMOL ORAL SUSPENSION 120mg/5ml FOR PREVENTION OF POST IMMUNISATION FEVER FOLLOWING ADMINISTRATION OF MENINGOCOCCAL GROUP B VACCINE (BEXSERO®)
PATIENT GROUP DIRECTION- SIGNED APPROVAL

GENERAL POLICY FOR COMMUNITY PHARMACIST SUPPLYING

PARACETAMOL ORAL SUSPENSION 120mg/5ml FOR PREVENTION OF POST IMMUNISATION FEVER FOLLOWING ADMINISTRATION OF MENINGOCOCCAL GROUP B VACCINE (BEXSERO®)

Immunisation against meningococcal serogroup B disease (MenB) has been 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.

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 that paracetamol should be given prophylactically when Bexsero® is given with the routine vaccines in infants under one year of age. Three 2.5mL doses of infant paracetamol suspension 120mg/5mL should be given orally, with the first dose provided as soon as possible after vaccination, and two subsequent doses at intervals of four to six hours.

In Scotland it has been agreed that community pharmacists will provide a supply of infant paracetamol oral suspension 120mg/5mL for prevention of post immunisation fever following childhood MenB vaccination as a new component of the Public Health Service. The supply will be available to any infant under **one year of age** scheduled to receive Bexsero® vaccine.

The parent/carer must be appraised of the need for them to provide medical information to allow the pharmacist to make an informed assessment of the suitability of the infant to receive paracetamol.

Pharmacists

Paracetamol oral suspension 120mg/5ml for prevention of fever following vaccination with MenB vaccine may **only** be supplied by a pharmacist. Medicine counter staff must be trained to refer each request for paracetamol oral suspension for prevention of fever following vaccination with MenB vaccine to that pharmacist.

Premises

The service can only be provided in a pharmacy which has a suitable area for consultation with patients. This should be a consultation room (or quiet area within the pharmacy if a room is not available).

Indemnity

The pharmacist must ensure that the organisation that provides their professional indemnity has confirmed that this activity will be included in their policy.

Patient Confidentiality

General Medical Council statement:

“Patients are entitled to expect that the information about themselves or others which a doctor learns during the course of a medical consultation, investigation or treatment, will remain confidential.

Any explicit request by a patient that information should not be disclosed to particular people, or indeed to any third party, must be respected save in the most exceptional circumstances, for example where the health, safety or welfare of someone other than the patient would otherwise be at serious risk”

Pharmacists *and their staff* must respect this duty of confidentiality and information should not be disclosed to any third party without the client’s consent.

Clinical Support

The pharmacist will not be working in isolation and must feel confident to refer to other sources of information and the patient's GP.

Adverse Drug Reaction (ADRs)

Healthcare professionals and carers are encouraged to report suspected adverse reactions to the Medicines and Health Products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on <http://yellowcard.mhra.gov.uk>

PATIENT GROUP DIRECTION FOR SUPPLY OF PARACETAMOL ORAL SUSPENSION 120mg/5ml FOR PREVENTION OF POST IMMUNISATION FEVER FOLLOWING ADMINISTRATION OF MENINGOCOCCAL GROUP B VACCINE (BEXSERO®) BY AUTHORISED COMMUNITY PHARMACISTS

Indication	Prevention of post immunisation fever following administration of meningococcal group B (MenB) vaccine (Bexsero®)
Inclusion Criteria	<p>Infants under 12months 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 and 4 months.</p> <p>Most infants will be greater than two months of age when presenting for first dose of MenB vaccine but a small number may be under 8 weeks old. These children are included.</p>
Exclusion Criteria	<p>Infants 12 months of age or over.</p> <p>Infants receiving MenB vaccine at 12 month booster dose.</p> <p>Infant known to have hypersensitivity to paracetamol or any ingredient in the product. Pharmacists must check the marketing authorisation holder's summary or product characteristics for details of a particular brand's ingredients.</p> <p>Infant known to have impaired liver or kidney function.</p> <p>Infant known to have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.</p> <p>Infant known to weigh less than 3kg.</p>
Referral criteria	Pharmacists should refer patients to their GP when there is any uncertainty over the suitability of the infant to be given paracetamol.
Caution	If a very preterm infant (born <32 weeks gestation) presents for their first immunisation in primary care seek advice from GP or specialist on dose if required.
Action if patient declines	Advise about the risk of fever following vaccination with Bexsero® and how to manage this – see patient advice section.
Action if Included	Supply 100ml of paracetamol oral suspension 120mg/5ml
Action if excluded	Refer to GP

Details of treatment course	Drug name	Paracetamol
	Strength and form	Oral suspension 120mg in 5ml
	Route	Oral
	Legal status	General Sales List
	Dose(s)	60mg (2.5ml of 120mg/5ml oral suspension)
Treatment regime	<p>Three doses of paracetamol are required</p> <p>60mg (2.5ml of 120mg/5ml) as soon as possible after vaccination with Men B vaccine.</p> <p>A second 60mg dose 4-6 hours after the first dose and,</p> <p>a third 60mg dose after a further 4-6 hours later.</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>	
Is the use outwith the SPC?	<p>Yes.</p> <p>This PGD authorises prophylactic use of paracetamol following Men B immunisation. It advises three 60mg (2.5ml of 120mg/5ml) 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 recommendations for prophylactic paracetamol doses following MenB vaccination with Bexsero®▼, 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>
Drug Interactions	<p>The clinical significance of any drug interactions in relation to the short term use of paracetamol indicated in this PGD is likely to be minimal and does not contraindicate paracetamol use.</p> <p>Avoid concomitant use of other paracetamol-containing products.</p>
Side Effects	<p>In the event of severe adverse reaction individual 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>Parent/carer 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>For full details/information on possible side effects, refer to the marketing authorisation holder's SPC or current BNF for children.</p>
Advice and Support	<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: A second dose of 60mg (2.5ml paracetamol suspension 120mg/5ml) should be administered 4-6 hours after the initial dose.</p> <p>A third dose of 60mg (2.5ml paracetamol suspension 120mg/5ml) should be</p>

	<p>administered 4-6 hours after the second dose.</p> <p>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 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"> • 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. <p>Pharmacists should advise that if the 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 of paracetamol.</p>
Informed Consent	<p>Parent/ carer must be informed that information relating to the supply of paracetamol under a PGD needs to be retained to ensure proper record keeping and patient safety.</p>
Records	<ul style="list-style-type: none"> • Patient's name, address, date of birth; • Date supplied & name of the pharmacist who supplied the medication; • Advice given to patient's parent or carer.

References	<p>Pharmacist operating the PGD must be familiar with:</p> <p>Current edition of BNF and BNF for Children</p> <p>Marketing authorisation holder's Summary of Product Characteristics https://www.medicines.org.uk/emc/</p> <p>Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</p> <p>Immunisation against Infectious Disease [Green Book] chapter 22 Meningococcal https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22</p> <p>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</p> <p>'What to expect after immunisation leaflet' http://www.immunisationscotland.org.uk/documents/6122.aspx</p>
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Authorisation

This Patient Group Direction gives authority for

(PRINT NAME of APPROVED PHARMACIST)

Providing services from

(NAME OF PHARMACY & CONTRACTOR CODE)

To supply paracetamol oral suspension 120mg/5ml to clients for prevention of fever following administration of meningococcal group B (MenB) vaccine (Bexsero®)

I understand that the requirements for a participating pharmacist include

- Having appropriate indemnity insurance
- Maintaining clinical knowledge appropriate to this practice by making myself aware of appropriate current literature
- Acting within the terms of the Patient Group Direction and supplying accordingly
- Providing the service from a pharmacy with a suitable private area for consultation.

Pharmacist's Signature: _____ **Date:** _____

Participating Pharmacists should sign this PGD and return a copy of this sheet by e-mail or ~~fax to~~ post to:

**Katie Kerr
Primary Care Contractors Organisation
Pentland House
47 Robb's Loan
Edinburgh
EH14 1TY**

e-mail: CommunityPharmacy.Contract@nhslothian.scot.nhs.uk