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

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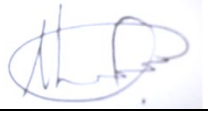
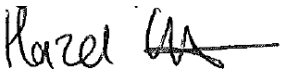
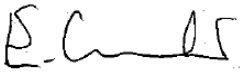
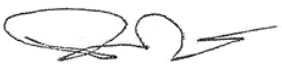
*** If this PGD is past its review date then the content will remain valid until such time as the PGD review is complete and the new issue published**

It is the responsibility of the person using this PGD to ensure that they are using the most recent issue.

Developed by	Designation	Signature	Date
Athan Tachtatzis	PGD Pharmacist NHS Fife		26.10.22
Hazel Close	Public Health Pharmacist NHS Fife		03.11.22
Dr Esther Curnock	Consultant in Public Health NHS Fife		31.01.23

This Patient group Direction has been approved on behalf of NHS Fife by:

Name	Designation	Signature	Date
Nicola Robertson	Associate Director of Nursing NHS Fife		03.02.23
Dr Philip Duthie	Clinical Director H&SCP NHS Fife		02.02.23
Fiona Forrest	Deputy Director of Pharmacy and Medicines		02.02.23

1. Clinical condition to which the patient group direction applies

Indication	• Prevention of post immunisation fever following administration of meningococcal group B (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 and 4 months. • Most infants will be greater than two months of age when presenting for first dose of MenB vaccine but a small number may be a few days under 8 weeks old. These children are included in this PGD. • Valid consent to treatment according to NHS Fife policy
Exclusion criteria	• Infants 12 months of age or over • Infants receiving MenB vaccine at 12 month booster dose • Infants 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 • Infants known to have impaired liver or kidney function • Infants known to have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency • Infants born at < 32 weeks and currently weigh less than 4kg • No valid consent to treatment according to NHS Fife policy
Cautions / Circumstances when further advice should be sought from a doctor	• Pharmacists should refer patients to their GP when there is any uncertainty over the suitability of the infant to be given paracetamol • If a very premature baby (born at <32 weeks) and currently weighing less than 4kg presents for supply of prophylactic paracetamol, Refer to GP This reflects dosing advice in the BNFc and Public Health Scotland leaflet 'What to expect after immunisation' http://www.healthscotland.com/documents/6122.aspx • 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 • Avoid concomitant use of other paracetamol-containing products • 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.
Action if excluded	• Do not use the PGD • The patient must be referred to an authorised prescriber
Action if patient declines treatment	• Advise about the risk of fever following vaccination with Bexsero® and how to manage this – see patient advice section

2. Medication details

Name strength & formulation of drug	• Paracetamol Oral suspension 120mg in 5ml
Route of administration	• Oral
Dosage	• 60mg (2.5ml of 120mg/5ml oral suspension)
Frequency of administration	• Three doses of paracetamol are required • 60mg (2.5ml of 120mg/5ml) at the same time or as soon as possible after vaccination with Men B vaccine • A second 60mg dose 4-6 hours after the first dose • A third 60mg dose after a further 4-6 hours later 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
Duration of treatment including maximum/ minimum period if applicable	• 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 the infant remains febrile 48 hours after immunisation medical advice should be sought to exclude other causes
Quantity to be supplied	• Supply 100ml of paracetamol suspension 120mg/5ml
Patient advice verbal and written	• Advise parent/carer that the dosing advice on the product supplied & the manufacturer's patient information leaflet may differ from the dosing advice recommended post MenB vaccination. • 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. • A third dose of 60mg (2.5ml paracetamol suspension 120mg/5ml) should be administered 4-6 hours after the second dose • 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 the infant remains febrile 48 hours after immunisation medical advice should be sought to exclude other causes • 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 • 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 aged a few days before 8 weeks 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 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
Black triangle drug▲	• No
Legal category	• General Sales List /P
Use outwith 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 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
Identification and management of adverse reactions	• 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 • 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 • For full details/information on possible side effects, refer to the marketing authorisation holder's SPC or current BNF for children • All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk

Storage requirements	• Store at room temperature 25°C
Additional information	• None
Monitoring if required	• Not applicable
Follow up with appt or GP	• Contact GP if fever persists and the infant remains febrile 48 hours after immunisation in order to exclude other causes.
Additional facilities/supplies required	• None
Disposal	• Any expired medicines should be returned to Pharmacy for safe disposal

3. Staff characteristics

Professional qualifications	• Pharmacist whose name is currently on the practising section of the pharmaceutical register held by the General Pharmaceutical Council (GPhC)
Specialist competencies or qualifications	• The pharmacist must maintain their own level of competence and knowledge in this area to provide the service
Continued training requirements	• The pharmacist must maintain clinical knowledge appropriate to their practice by attending relevant study days, courses and to make themselves aware of appropriate current literature

4. Referral arrangements/Audit trail

Arrangements for referral to medical advice	• The patient may be referred to a doctor at any stage, if this is necessary, in the professional opinion of the pharmacist • Patients should be referred to the doctor if treatment proves to be ineffective in relieving the symptoms
Records/Audit trail	• The pharmacist will complete a CP(US) or CP4 form • The 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
References/ Resources & comments	• Paracetamol 120mg/5ml suspension SPC https://www.medicines.org.uk • 'What to expect after immunisation leaflet' http://www.healthscotland.com/documents/6122.aspx • All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) • BNF / BNFc latest edition available at www.medicinescomplete.com • NHS Fife Consent Policy • NHS Fife Safe and Secure use of Medicines Policy and procedures (SSUMPP)

This Patient Group Direction has been assessed for Equality and Diversity Impact

5. Management and monitoring of patient group direction

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 patients 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
- To work in a registered approved pharmacy

Pharmacist's Signature: _____ GPhC Number _____ Date: _____

Participating Pharmacists should sign this PGD and return a copy of this sheet

by e-mail to PGD Administrator fife.pgd@nhs.scot

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