Patient Group Direction template

Administration of Paracetamol 120mg/5ml suspension

This specimen patient group direction (PGD) template has been produced by Health Protection Scotland to assist NHS Boards

NHS Boards should amend/adapt this PGD template and must ensure that the PGD is considered and approved in line with local clinical governance arrangements for PGDs

PGD Paracetamol 120mg/5ml suspension

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Health Protection Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer paracetamol 120mg/5ml suspension under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS (*insert details*) by

Doctor		Signature	
Pharmacist		Signature	
Nurse		Signature	

Approved on behalf of NHS (*insert details*) by

Medical Director		Signature	
Director of Pharmacy/Senior Pharmacist		Signature	
Clinical Governance Lead		Signature	

Date Approved _____

Effective from	01/09/2015	Review Date	31/07/2017

Clinical Situation

Indication	Prevention of post immunisation fever following administration of meningococcal group B conjugate (Bexsero®) vaccine.
Inclusion Criteria	Individuals (born on or after 1st July 2015) requiring Bexsero® as part of primary vaccination as part of the routine immunisation schedule. Individuals attending routine age three month or four month immunisation visits (born from 1st May 2015 to 30th June 2015) of age at start of vaccination programme (1st September 2015) requiring Bexsero® vaccine as part of the catch up programme. Valid consent has been given to administer paracetamol.
Exclusion Criteria	Known hypersensitivity to paracetamol or any other ingredient in the product. Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of particular brand's ingredients. Known impaired liver or kidney function. Known to have taken paracetamol containing products within the previous four hours. Known to have taken four or more doses of paracetamol in the previous 24 hours. Infant weighs less than 3kg.
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Where there is any uncertainty over suitability of the infant to be given paracetamol. If infant weighs less than 3kg advice should be sought from hospital neonatologist. If infant is <32 weeks corrected gestational age at the time of vaccination advice should be sought from hospital neonatologist. Some brands of paracetamol suspension contain sorbitol liquid and maltitol liquid which means those brands are unsuitable for those known to have inherited intolerance to fructose.
Action if Excluded	In GP practice setting, inform or refer to GP. Document in clinical records**.**
Action if Patient Declines	Advise about the risk of fever following vaccination with Bexsero®. Document advice given and decision reached. In GP practice setting, inform or refer to GP.

Description of Treatment

Name of Medicine	Paracetamol
Form/Strength	Oral suspension 120mg/5ml
Route of administration	oral
Dosage	60mg (2.5ml of 120mg/5ml suspension)
Frequency	Single dose
Duration of treatment	Single dose
Maximum or minimum treatment period	Single dose
Quantity to supply/administer	Single dose
▼ black triangle medicines	No
Legal Category	GSL for pack size 100ml P for pack size 200ml
Is the use outwith the SPC	The SPC states that paracetamol suspension should not be given to babies less than 2 months of age and that two doses may be given for post immunisation fever. The recommendation for three doses of paracetamol to be given to infants under 1 year attending for Bexsero® vaccination is aligned with Scottish Government policy which is based on recommendations in the Green Book. The recommendation for three doses is also supported by the Commission for Human Medicines. 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.
Storage requirements	Store in a locked cupboard: do not store above 25C. Add date that bottle was opened for first time. Replace any un-used paracetamol suspension three months after pack was opened for first time.
Additional Information	Shake well before use and measure dose with an oral syringe.
Warnings including possible adverse reactions and management of these	Adverse reactions are rare but rashes have been reported 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.

Reporting procedure for adverse reactions	Any adverse events that are serious or result in harm that may be attributable to paracetamol 120mg/5ml suspension should be reported using the yellow card system on http://yellowcard.mhra.gov.uk/ Any serious adverse reaction should be documented in an individual's record. GP should also be informed.
Advice to Patient/carer including written information	Inform parent/carer that further doses of paracetamol should be given 4-6 hours after the first dose and 4-6 hours after the second dose. Provide prescription for supply of paracetamol 120mg/5ml suspension if required. Give advice on monitoring of temperature and measures to lower temperature. Advise individual to seek medical advice in case of severe fever.
Monitoring	Following immunisation patients remain under observation in line with NHS Board policy.
Follow-up	Not applicable.
Additional Facilities	Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection. Access to a telephone.

Characteristics of staff authorised under the PGD

Professional qualifications	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions.
Specialist competencies or qualifications	Approved by the organisation as competent: • to undertake immunisation and discuss issues related to immunisation, • to assess the person's capacity to understand the nature and purpose of the immunisation in order to give or refuse consent, • to work with this patient group direction, • in the recognition and management of anaphylaxis,
Continuing education and training	The practitioner must be familiar with the SPC for paracetamol suspension being administered in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of immunisation and in the recognition and management of anaphylaxis.

Audit Trail

Record/Audit Trail	The approved practitioner must ensure maintenance of records for each dose administered and may be required to share information with appropriate parties in line with confidentiality protocols.The information relating to each individual must include as a minimum:

	• Patient's name and date of birth, • Name and strength of the brand used • Dose, • Date given and by whom (name/signature). All records must be clear and legible and, ideally, in an easily retrievable format. Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • GP practice computer, • Individuals GP records, • Child Health Systems (e.g. SIRS) • Personal Held Child Record (red book)
Additional references	Practitioners operating the PGD must be familiar with: Department of Health (2006): Immunisation against Infectious Disease [Green Book] Immunisation against Infectious Disease [Green Book] chapter 22 Meningococcal Current edition of BNF and BNF for Children Marketing authorisation holder's Summary of Product Characteristics All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) NMC (2015) Code of Professional Conduct. NMC (2010) Standards for Medicines Management

PGD for administration of paracetamol 120mg/5ml suspension- Authorisation

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the manufacturer's summary of product characteristics for all medicines administered in accordance with this PGD.

Note to Authorising Managers

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I agree to administer paracetamol suspension 120mg/5ml only in accordance with this PGD.

Name of Professional	Signature	Date

I agree that the professionals listed above are authorised to supply/administer medicines in accordance with this PGD to patients cared for in this service area.

Lead Clinician for the service area (Doctor)		
Name:	Signature:	Date: