# Patient Group Direction (PGD) for the Administration of

# COMBINED HAEMOPHILUS INFLUENZA TYPE B + MENINGICOCCAL GROUP C CONJUGATE VACCINE (Hib+MenC – Menitorix®)

by Registered Professionals to Individuals Accessing NHS Services in
Durham, Darlington, Tees, North Cumbria, Northumberland and Tyne & Wear

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

Direction Number: - **NECSAT 2018/003**
Valid from: 1st July 2018
Review date: 1st April 2020
**Expiry date: 30th June 2020**

| **This patient group direction has been developed & produced by: -** | | | |
|---|---|---|---|
| Title | Name | Signature | Date |
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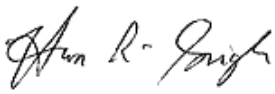
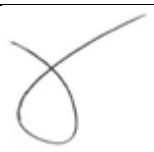
| Medicines Optimisation Pharmacist (North of England Commissioning Support) | **Hira Singh** *(Senior Pharmacist)* |  | 21/06/18 |
| *Assistant Medical Director* (NHS England, Cumbria and North East) | **Dr James Gossow** *(Senior Doctor)* |  | 21/06/18 |
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Development supported by:
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| **This PGD has been approved for use in Cumbria, Northumberland, Tyne & Wear by: -** | | | |
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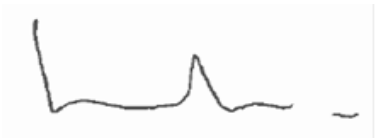
| *Deputy Medical Director* (NHS England, Cumbria and North East) | **Dr Jonathan Slade** *(Governance Authorisation)* |  | 28/06/18 |

# 1. Clinical Condition or Situation to Which the Direction Applies

## Indication (defines situation or condition)

Active immunisation vs. invasive disease caused by Haemophilus Influenza Type B (Hib) & Neisseria Meningitis serotype C (Men C)

## Objectives of care

- To prevent infectious disease, promote health and reduce morbidity and mortality

## Inclusion criteria (Also refer to updated chapters 7, 16 and 22 of the PHE "The Green Book" on line version)

**Only use those criteria that are specific to your authorised role & competence.**
**Ensure appropriate consent has been obtained before commencing any vaccination.**

### Current nationally recommendations include: -

- **As reinforcing (booster) dose** at 12 months of age for children who have received a complete primary course of three Hib-containing vaccine injections, (part of the routine schedule)
- **As a booster dose** for children aged 12 months to under 10 years of age and require a booster following a primary course of Hib and MenC immunisation (this booster is offered at around 12months of age as part of the routine schedule)
- **As a booster dose** in all children from 12 months old to the age of ten years, irrespective of their primary vaccination history;
- **For individuals with unknown or incomplete vaccination histories : -**
  - Infants from 2 months of age up to their first birthday may receive any missing doses of Hib as Hib/MenC and receive the 12-13 month Hib/MenC booster, ensuring at least one month interval between MenC and Hib/MenC,
  - For children aged 12months to less than 2 years and unvaccinated for Hib should receive a single dose of Hib/MenC
  - For children aged two to less than ten years of age who have not received a Hib/MenC since their first birthday and are unvaccinated for Haemophilus influenzae type b (Hib) should receive a dose of Hib/MenC
  - For children aged one year to less than 10 years of age should receive a single dose of a MenC containing vaccine. since single MenC will no longer be supplied for the UK programme, combined Hib/MenC vaccine should be used
- **For children aged 2 months to under 10 years of age and are unimmunised or incompletely immunised against *Haemophilus influenzae* type b**
  - **From 2 months of age to 1st birthday**:
    - When Hib has not been given as part of the primary course and no other component is required (i.e. no D, T, aP or IPV), then three doses of Hib/MenC can be given;
    - When neither Hib nor MenC have been given as part of a primary course but child has received 3 doses of DTaP/IPV, then 3 doses of Hib/MenC can be given;
  - **From 1st up to 2nd birthday:**
    - Where DTaP/IPV has been given when DTaP/IPV/Hib not available, give Hib/MenC instead of MenC at first appointment.
  - **From 2nd up to 10th birthday:**
    - Where DTaP/IPV has been given when DTaP/IPV/Hib not available, give Hib/MenC instead of MenC at the first appointment.
- **For children and adults with asplenia, splenic dysfunction, immuno-suppression or complement deficiency:**
  - Children presenting less than 2yrs of age who have been immunized according the UK routine childhood schedule, which includes a booster of Hib/MenC at 12months, receive additional dose of Hib/MenC after their 2nd birthday.
  - Fully vaccinated children presenting over two years of age require an additional dose of Hib/MenC.
  - Children presenting over two years of age and adults require an additional dose of Hib/MenC. **(NB. Ensure that the child has been immunized according to national schedule, including the 12 month boosters)**

## Exclusion criteria

- Children under 2 months of age;
- No valid consent (where applicable);
- Have received Hib or MenC containing vaccine in the preceding 4 weeks
- Patient is acutely unwell (postpone vaccination until recovered. Minor infections without fever or systemic upset are not reasons to postpone immunisation).
- A confirmed anaphylactic reaction to a previous dose, or constituent, ingredient or excipient of the vaccine or component vaccines.
- Severe hypersensitivity to any ingredient or component of the combined or component vaccines, including tetanus toxoid **(please also refer to precautions section).**

***Refer to current SPC, Green Book online version) and current BNF for full list of details.***

## Precautions

- Hypersensitivity reactions to previous dose of vaccine or component of vaccine:
  - **Please note.** "Local adverse reactions that generally start within a few hours of the injection and are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens
- **Important note:** Individuals 12 months old and over, who are to receive Eculzimab therapy should receive 1 dose of Hib/MenC vaccine at least 2 weeks prior to commencement of therapy.
- If a seizure associated with a fever occurred within 72 hours of a previous immunisation, immunisation should continue as recommended if a cause is identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable.
- Use the vaccine with caution for individuals with thrombocytopenia or any coagulation disorder (see legal status information below)

## Action if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

## Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria
- Patient requires additional information in order to decide whether or not to have the vaccination

## Action if vaccination refused

- Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

# 2. Description of treatment

## Name, strength & formulation of drug

**Menitorix** ® (Glaxo Smith Kline UK): **Haemophilus Influenza type b + Meningococcal Group C conjugate vaccine (Hib/MenC)**

- Powder in a vial (type I glass) with a stopper (butyl rubber) + 0.5 ml of solvent in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) with or without separate needles (pack size of 1 or 10 vials).
- The reconstituted vaccine is a clear and colourless solution. (See BNF &/or individual Manufacturer's SPC for further details)

## Legal Status:

**POM –**Prescription Only Medicines

The Administration of Menitorix® vaccine under this PGD to children over 2 years of age is off label, but follows current (Public Health England) Green Book recommendations (on line version – for further detail please refer to reference section).

The Menitorix® SPC states: "The timing of the booster dose should be from the age of 12 months onwards and at least 6 months after the last priming dose." However, when primary vaccination has been delayed, this first booster dose may be given at the scheduled visit provided it is at least 1 month since the last primary dose was administered in accordance with PHE recommendations for the vaccination of individuals with uncertain or incomplete immunisation status.

Administration of Menitorix® by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 of "The Green Book".

## Dosage /Dose range

| | | |
|---|---|---|
| **Menitorix ®** | **2 months old and over:** | **0.5ml** |

## Route/Method

- The vaccine must be reconstituted in accordance with the manufacturer's instruction prior to administration (refer to SPC or PIL)

**Intra-muscular (IM) injection** is the preferred route

- Anterolateral thigh in infants; deltoid region in older children, adolescents and adults.
- Not to be given intravenously.
- For individuals with a bleeding disorder, e.g. thrombocytopenia the vaccine should be given by deep subcutaneous injection.
- If given at the same time as other vaccines it should be given at separate sites, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart

**(Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).**

## Frequency of Administration

| AGE | Patient Group & Frequency of Injection |
|---|---|
| **12 months old**<br>(within one month after the 1st birthday) | **1 single booster dose,** as part of the routine immunisation UK schedule. |
| **12 months to under 10 years old** | **1 single dose** (for those who have fallen outside routine schedule)<br>**1 single dose** for previously unvaccinated or partially vaccinated children against Hib or MenC |
| 2 months to under 1 years old<br>(if presenting with uncertain or incomplete immunisation status) | Any **missing doses** can be given as Hib/MenC at monthly intervals as as defined in the PHE "Vaccination of individuals with uncertain or incomplete immunisation status" September 2015 document |

| **Adults and Children with Asplenia, Splenic Dysfunction and Complement disorders (including those receiving complement inhibitor therapy)**<br>(Please also refer to Green Book, Chapter 7 for "Immunisation of individuals with underlying medical conditions") | |
|---|---|
| **When first acquired/diagnosed** | **Dose** |
| First presenting **- under 2 years old** | **1st single dose** as part of routine childhood schedule.<br>An additional **2nd single dose** after the 2nd birthday. |
| First presenting: **- from 2 to under 10 years of age** | Ensure that the child has been immunized according to national schedule, including the 12-month boosters and they should also receive:<br>**1 single additional dose** |
| First presenting: **- at 10 years old onwards**<br>(regardless of previous vaccination) | **1 single dose** |

**NB.** See "Special considerations/additional notes" section & "The Green Book," chapters 7, 16 & 22 (online version) for full details.

Please also see **The Complete Routine Immunisation Schedule** using the following link:

https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule

## Maximum dose and number of treatments

**Maximum dose is 0.5ml**

**Maximum No. of doses = 3 doses** (routinely this is 1 dose)

## Follow up treatment

**As above**

(See also Immunisation Against Infectious Diseases (Green Book on-line); updated chapters 16 and 22)

# 3. Further Aspects of Treatment

## Relevant Warnings & Potential Adverse Effects

**Relevant Warnings: -** See manufacturers SPC for full details / current Green Book online Chapter 9,16 & 22

**Potential Adverse Effects/ Reactions: -** Usually transient and only last a few days after vaccination.

**Please be aware of Resuscitation Council Guideline changes (2016)**

| | |
|---|---|
| **Very common & common reactions** | Tenderness, swelling, redness and pain at the injection site (including induration & nodule)<br>Irritability, drowsiness and loss of appetite. Fever ( rectal ≥ 38 °C) |
| **Uncommon effects** | Vomiting, diarrhoea, crying , fever (rectal ≥ 39.5°C), dermatitis atopic and rash. |
| **Rarely** | Abdominal pain, insomnia Malaise and anaphylaxis |

This list is not exhaustive. Please also refer to current manufacturers SPC for details of all potential adverse reactions.

## Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Advice on management including anaphylaxis: - Chapter 8 of the Green Book provides detailed advice on managing adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist if appropriate

## Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.

  See manufacturers SPC for details of all potential adverse reactions.

## Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine. Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure. Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record

## Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate

## Records

In all cases manual records including the Personal Held Child Record, computerised records and data collection for Child Health Information Services (CHIS) should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Confirmation that consent has been obtained;
- Dose, site and route of injection;
- Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications;
- That side effects have been discussed;
- Support literature given (where applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

## Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store vaccine in a refrigerator (+2°C to +8°C). Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

## Special Considerations / Additional Information

- Hib+MenC vaccine can be administered simultaneously with other vaccines including the pneumococcal conjugate and MMR vaccines, as long as different needles and injection sites are used, preferably in a different limb or at least 2.5cm from the concomitant immunisation.
- For children over one year of age and under ten years of age who have either not been immunised or not completed a primary course of diphtheria, tetanus, pertussis or polio, DTaP/IPV/Hib vaccination should be used (refer to PHE guidance for individuals with uncertain or incomplete immunisation status)
- The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate.

## References


- NICE Good Practice Guidance : Patient Group Directions - Aug 2013 updated March 2017 https://www.nice.org.uk/guidance/mpg2 Accessed 29.3.18
- Public Health England: Immunisation Against Infectious Disease (01/09/15) – The Green Book; Chapter 22 v6_0, Meningococcal (September 2015) and Chapter 16, Haemophilus influenzae type b (Hib) (March 2011) and Chapter 7, Immunisation of individuals with underlying medical conditions. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Accessed 29.3.18
- Public Health England: The complete routine immunisation schedule (2016); https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule Accessed 29.3.18
- British National Formulary (BNF) http://www.bnf.org/bnf/index.htm Accessed 29.3.18
- Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
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- Nursing and Midwifery Council (NMC), 2008: Code of Professional Conduct: standards of conduct, performance & ethics for nurses & midwives.
- Resuscitation Council (UK), October 2010: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Glaxo Smith Kline UK , Menitorix ® - Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) - Electronic Medicines Compendium https://www.medicines.org.uk/emc/product/167 Accessed 29.3.18

## 4. Characteristics of Healthcare Professional Staff

**Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.**

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

| | | |
|---|---|---|
| Pharmacists | Nurses | Chiropodists/Podiatrists |
| Health Visitors | Physiotherapists | Midwives |
| Dieticians | Optometrists | Registered Orthoptists |
| Prosthetists and Orthotists | Radiographers | Occupational Therapists |
| Speech and Language Therapists | Dental Hygienists | Dental Therapists |
| State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval. | | |

### **Qualifications required (**professional registration applies to specific professions**)**

**Professionals using this PGD must be currently registered with their relevant professional body, e.g.**

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

### **Additional requirements** (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

### **Continued training requirements** (applies to all staff)

- Annual attendance at an accredited update on resuscitation skills and the management of anaphylaxis within the community/primary care **(mandatory).**
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation **(recommended).**
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

## Individual Healthcare Professional Authorisation

***This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.***

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

is authorised to administer

**Combined Hib+MenC Vaccine ( Menitorix ® )**

……under this Patient Group Direction (NECSAT 2018/003)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

**Authorisation to use this PGD by: -**

This above named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

| PGD Valid from: 1st July 2018 | Review Date: - April. 2020 | **Expiry Date: - 30th June 2020** |
|---|---|---|

# Management & Monitoring of Patient Group Direction NECSAT 2018/003

**COMBINED HAEMOPHILUS INFLUENZA TYPE B + MENINGICOCCAL GROUP C CONJUGATE VACCINE (Hib+MenC – Menitorix®)**

## Healthcare Professional Authorisation (service/practice list)

***This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.***

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

**Combined Hib+MenC Vaccine (Menitorix®)** under the Patient Group Direction (NECSAT 2018/003)

**PGD Valid from date: 1st July** 2018 **PGD Expiry Date:** 30th June 2020

| **Healthcare Professional** | | | **Authorised by:** | | |
|---|---|---|---|---|---|
| **Name** | **Signature** | **Date** | **Name** | **Signature** | **Date** |
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| PGD Valid from: 1st July 2018 | Review Date: - April 2020 | **Expiry Date: - 30th June 2020** |