

Administration

PATIENT GROUP DIRECTION (PGD) FOR

## Hepatitis A and B Vaccine

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

<b>Clinical Condition</b>	
<b>Indication</b>	Individuals using Sexual Health services requiring active immunisation against infections caused by both Hepatitis A and Hepatitis B viruses.
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>◦ Age 16 and above.</li> <li>◦ Injecting drug users</li> <li>◦ People going to reside in, or travel to areas of high or intermediate prevalence and whose sexual behaviour places them at risk</li> <li>◦ Men who have sex with men, who have not previously been vaccinated against Hepatitis A</li> <li>◦ If primary schedule, all pre-vaccination serology reviewed and no natural immunity to Hepatitis B.</li> <li>◦ Individuals infected with Hepatitis C infection, with no documented evidence of immunity to Hepatitis B and no history of Hepatitis A vaccination</li> </ul> <p>All other indications as found in the DH immunisation against infectious diseases (Green Book) are not covered by this Patient Group Direction and require a Patient Specific Direction from a prescriber</p>
<b>Exclusion criteria</b> If any of the following apply the PGD CANNOT be used and the patient must be referred to a prescriber	<ul style="list-style-type: none"> <li>◦ Age under 16 years. Young people under 16 should be considered on an individual basis and where appropriate, a licensed paediatric Hepatitis A &amp; B combined vaccine can be dispensed on a named-patient basis. This requires a prescriber and is <u>not</u> covered by this PGD</li> <li>◦ No valid consent</li> <li>◦ Previous confirmed Hepatitis A infection</li> <li>◦ Acute hepatitis B or individuals known to have markers of current infection</li> <li>◦ Individuals with a fever or acute severe systemic illness - immunisation should be delayed</li> <li>◦ Pregnancy and breast feeding (see Summary Product Characteristics)</li> <li>◦ Confirmed anaphylactic reaction to a previous dose of the combined vaccine or Hepatitis A or Hepatitis B vaccine or any component of the above vaccines (eg neomycin, ovalbumin)</li> <li>◦ Hepatitis C infected individuals with known immunity to Hepatitis B should be offered Hepatitis A vaccine instead.</li> <li>◦ Not to be used for post exposure prophylaxis e.g. needle</li> </ul>

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	<p>stick injury - obtain advice from public health officer on call or local health protection unit or virologist</p> <ul style="list-style-type: none"> <li>◦ Immunosuppressed individuals, including individuals on cortisone treatment/chemotherapy/radiotherapy - may need a different dose or regime under a Patient Specific Direction from a doctor</li> <li>◦ Individuals with chronic renal failure including those on haemodialysis. These may require a higher dose of hepatitis B vaccination.</li> </ul>
<b>Seek further advice and document advice and action</b>	Individuals with severe (anaphylaxis) latex allergy – call manufacturer to check whether the batch has any latex contamination.
<b>Further Information</b>	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.
<b>Action if patient declines or is excluded</b>	Reschedule vaccination if patient acutely unwell Inform or refer to doctor as appropriate.

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<b>Drug Details</b>	
<b>Name, form &amp; strength of medicine</b>	Inactivated Hepatitis A and surface antigen Hepatitis B vaccine Twinrix Adult 720 ELISA units (20 microgram in 1ml)
<b>Legal status</b>	Prescription Only Medicine (POM)
<b>Route/Method</b>	Shake the vaccine to produce a slightly opaque, white suspension. By intramuscular injection into the upper arm. Individuals with a bleeding disorder should be considered for deep subcutaneous injection due to risk of bleeding. Can be given at the same time as other vaccines such as Td/IPV, but at separate sites (at least 2.5cm apart), preferably different limbs. Never to be used for intravascular injection
<b>Dosage</b>	1.0ml
<b>Frequency</b>	The primary course is three doses Standard regimen is zero, 1 and 6 months When rapid protection against hepatitis B is required, because of concerns with adherence, use zero, 7 and 21 days and 12months. Primary course should be completed with the same vaccine Booster doses using monovalent vaccines at 5 years for hepatitis B and 20 years for hepatitis A
<b>Side effects</b>	Commonly pain, redness and swelling at the injection site Fever, malaise, fatigue, headache, nausea, loss of appetite, arthritis, arthralgia, and myalgia have been reported.
<b>Advice to patient/carer</b>	Provide manufacturers patient information leaflet Advice on the control of fever following vaccination. It is <b>not</b> recommended to use paracetamol or ibuprofen to prevent fever since this may lower response to vaccine.
<b>Further Information</b>	Obesity (defined as BMI $\geq 30$ kg/m <sup>2</sup> ) has been observed to reduce the immune response to hepatitis A vaccines. A number of factors have been observed to reduce the immune response to hepatitis B vaccines. These factors include older age, male gender, obesity, smoking, route of administration, and some chronic underlying diseases.

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<b>Staff Characteristics</b>	
<b>Professional qualifications</b>	Nurses on the NMC Register
<b>Specialist competencies or qualifications</b>	Has a working knowledge of, AND access to, the Department of Health website 'Immunisation against infectious diseases' Has undertaken appropriate training for working under PGDs for the supply and administration of medicines Has undertaken training in the management of anaphylaxis
<b>Continuing education &amp; training</b>	It is the responsibility of the individual to keep up-to-date with clinical developments as part of their CPD.
<b>Referral Arrangements and Audit Trail</b>	
<b>Records/audit trail</b>	Patient's name, address, date of birth Dose and form administered, batch details and expiry date Site of injection if more than one given Advice given to patient (including side effects & self care) Signature/name of staff who administered the vaccination Details of any adverse drug reaction and actions taken including documentation in the patient's medical record
<b>References/Resources and comments</b>	Current version of Immunisation against Infectious Diseases and updates. Department of Health website (Green Book): Summary of Product Characteristics. BNF.
<b>Clinical Authorisation</b>	
<b>Lead Doctor</b>	Dr Sumit Bhaduri, Deputy Medical Director & Consultant in GUM  Signature:  Date: 4/1/18
<b>Lead Pharmacist</b>	Dr Alex Johnson, Prescribing Support Pharmacist  Signature:  Date: 17.1.18
<b>Organisational Authorisation</b>	
<b>On behalf of WHCT</b>	Michelle Clarke, Director of Nursing & Quality  Signature:  Date: 12/1/18

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### Individual Authorisation

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 their own Code of Professional Conduct.**

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. Authorising managers should be sure that staff signed up to use the PGD have the necessary competence, training and knowledge to apply it.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD. I confirm that I have the necessary competence, training and knowledge to apply it.

<b>Name of Professional</b>	<b>Signature</b>	<b>Authorising Manager</b>	<b>Date</b>