Immunoglobulin Handbook

Hepatitis A

SUBGAM (HUMAN NORMAL IMMUNOGLOBULIN (HNIG))

(Gammaglobulin for subcutaneous or intramuscular injection) 750mg
Dispensed in vials of: 750mg (approximately 5ml) supplied by BPL

Indications

1. HNIG has limited use now and vaccine is usually recommended with or without HNIG. HNIG is no longer recommended at all for travel prophylaxis. On the basis of available evidence, travellers can be vaccinated with hepatitis A vaccine even up to the day of travel.

   Please note that hepatitis A antibody levels in SubGam are below the WHO standard of 100iu/ml and therefore the dose required to prevent or modify hepatitis A infection is higher than for previous products (see below).

2. For the protection of hepatitis A in household and other close contacts:

   Definition of a close contact:

   Individuals who are at high risk of being exposed to hepatitis A through close contact with the index case during the infectious period. A risk assessment should be undertaken to identify close contacts, with particular consideration of those that have shared food and toilet facilities with the index case, equivalent to a household type exposure. There should be a low threshold for considering someone a close contact. Close contacts may include:

   - A person living in the same household as the index case or regularly sharing food or toilet facilities with the index case during the infectious period, including extended family members and friends who frequently visit the household. This may also include those in shared accommodation with shared kitchen and/or toilet facilities.
• If the index case is a child in nappies or requiring assistance with toileting, any person who has been involved in nappy changing or assistance with toileting including nursery school staff and childminders during the infectious period.
• A person who has had sexual contact with the index case during the infectious period. Same room contacts in a pre-school child-care setting and reception class if the index case is a child, such as those working or being cared for in the same room as the index case during the infectious period.
• In long stay care facilities close contacts may include those sharing toilets, facilities or food with the index case, and those who were assisted with activities of daily living (such as eating and toileting) by the index case during the infectious period.
• Individuals injecting drugs and sharing injecting paraphernalia with the index case.
• The risk of transmission in all settings should be assessed on a case by case basis by the local senior health protection lead.

i. Vaccine should be given within two weeks of exposure if no previous history of hepatitis A vaccine or laboratory confirmed hepatitis A infection.

ii. HNIG is recommended in addition to vaccine for contacts who are less able to respond to vaccine (those aged 60 or over, those with immunosuppression and those with a CD4 count <200 cell per microlitre) and those at risk of severe complications (those with chronic liver disease including chronic hepatitis B or C infection.

For those exposed between two and four weeks ago, HNIG may be offered to modify disease in those at risk of severe complications (those with chronic liver disease including chronic hepatitis B or C infection).

Definition of time since exposure

• In the case of continuous exposure (such as contacts in a shared household), the limit for administering prophylaxis should be timed from the onset of jaundice or onset of symptoms such as fatigue, nausea, fever in the absence of jaundice.
• In the case of single exposure in the infectious period, time since exposure should be calculated from day of the exposure to the index case in their infectious period.
• In the case of intermittent exposure (such as contacts from school or hospital) time since exposure is define as the last day of exposure to the index case in their infectious period.

Where jaundice is not reported a history of dark urine or pale stools should be enquired about if there are no symptoms of jaundice, onset of other symptoms (such as fatigue, nausea, and fever) should be used.
HNIG may be used in addition to vaccine for individuals at increased risk (see above) who are exposed during outbreaks.

Dosage
The volume of SUBGAM is being recommended to provide levels of antibody equivalent to that achieved with products meeting the WHO standard.

<10 years  500mg  by intramuscular
≥10 years  750mg  injection

Hepatitis A vaccine may be administered simultaneously with human normal immunoglobulin but should be given at separate injection sites.

For further guidance on control of hepatitis A infection, see: https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance

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Algorithm for Management of Susceptible Close Contacts

Susceptible close contact of case of hepatitis A

- **≤14 days post exposure**
  - Chronic liver disease (inc chronic Hep B and/or C) or immuno-suppressed or HIV positive with a CD4 count <200 cells/mm³
    - Hepatitis A vaccine + HNIG**
  - Previously Healthy
    - <12 months
      - Vaccinate carers*
    - 12 months – 59 years
      - Hepatitis A vaccine
    - ≥ 60 years
      - Hepatitis A vaccine + HNIG**

- **>14 days post exposure**
  - Chronic liver disease
    - Hepatitis A vaccine + consider HNIG** if <28 days post exposure
  - Previously Healthy
    - One contact in household
      - Non-food handler
      - Hygiene advice only
    - Contact is a food holder
      - Risk assess Box 12
    - >1 contact in household
      - Hepatitis A vaccine to each unvaccinated household contact 12 months and over to prevent tertiary cases up to 8 weeks

* if unfeasible those aged ≥2 months should be immunised (unlicensed)
** if feasible testing for anti-HAV IgG should be done prior to administration of HNIG