Travel Health: Reimbursement (England & Wales)

Contents prepared and approved by GlaxoSmithKline
Intended for a Healthcare Professional audience

Please find product Prescribing Information at the end of this presentation

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Travel Health: Reimbursement
Learning objectives

- Know which travel vaccinations are to be given as part of NHS provision, which ones should be charged for privately and which ones can either be given on the NHS or charged for privately
- Understand when Hepatitis B can be given as part of NHS provision or charged for privately
- Understand the process of reimbursement in England and Wales
Vaccination Guidance

- The Green Book advises you **what** to give and **when**.
- The NHS regulations tell you **how** to give.
The GPC divides travel vaccinations into three categories:

- Those that must **always** be given as part of NHS provision through GMS Additional Services.
- Those that **cannot** be given as part of NHS provision.
- Those that can be given **either** on the NHS or privately.

Travel vaccinations that must always be given on the NHS:

- Hepatitis A - first and second dose.
- Combined hepatitis A and B - all doses.
- Typhoid - first and any subsequent doses.
- Combined hepatitis A and typhoid - first dose (second dose monovalent hepatitis A).
- Tetanus, diphtheria and polio given as combined Td/IPV vaccine.
- Cholera

General Practitioners Committee (GPC) Guidance

Travel vaccinations that cannot be given on the NHS:

- Yellow fever (must be given by registered centre)
- Japanese encephalitis
- Tick-borne encephalitis
- Rabies

Travel vaccinations that can either be given on the NHS or privately:

- Hepatitis B (monovalent) any dose
- Meningitis ACWY (quadrivalent meningococcal meningitis vaccine; A,C,Y and W135)

Hepatitis B

- There is a lack of clarity over when practices can charge for giving Hepatitis B vaccination.
- Hepatitis B vaccination can be given for the following purposes:
  - Travel
  - Occupational health
  - Medical reasons (e.g. IV drug use for renal disease)
- Hepatitis B vaccination for travel purposes is not remunerated by the NHS, however neither do the regulations say that it must be given on a private basis.
- Schedule 5 of the NHS (General Medical Services Contracts) Regulations 2004 states that:

  "The contractor may demand or accept a fee or other remuneration.... for treatment consisting of an immunisation for which no remuneration is payable by the Primary Care Trust and which is requested in connection with travel abroad"

Hepatitis B

• It is therefore up to individual practices to decide whether to give single (as opposed to combined) hepatitis B immunisation for travel on the NHS or privately.

• Combined hepatitis A and B immunisations must always be given on the NHS, but it must be clinically appropriate to give both.
  • The NHS regulations (2004) state that practices may charge for hepatitis B immunisations.
  • Hepatitis B vaccination for travel purposes is not included in the global sum

Hepatitis B

- An employer has a duty to assess the risk of contracting Hepatitis B through the workplace and to respond to that risk.

- A practice has no obligation to give Hepatitis B for occupational health risk – that’s the employer’s responsibility.*

- If a practice does so they cannot charge their patient. However practices can contract with the employer so to do.*

- Patients who require hepatitis B vaccination because of lifestyle or medical conditions should be vaccinated. In this instance, immunisation is included within the global sum and patients must not be charged.

Are there exceptional cases?

• Practices which charge a private fee for Hepatitis B immunisation need to either be consistent in doing so or need to have a policy regarding any exceptions.

• Such exceptions might include
  • Visiting friends and relatives (VFRs) travelling back to countries like Pakistan & India where their risk of contracting Hepatitis B may be high
  • Gap year students travelling to high risk destinations

• Hepatitis B can still be given as an NHS service and reimbursement claimed.

• The lack of a fixed regulation means there will be inconstancies from practice to practice and patients will often find this frustrating.
Malaria

• Anti-malarials can be prescribed or sold directly to patients
• Chloroquine /proguanil is available over the counter without prescription, but can also be dispensed and charged for.
• Atovaquone/proguanil, doxycycline and mefloquine are available on private prescription or they too can be sold and dispensed.

Other Travel Health charges

Charges can also be made for the following:

• Fitness to travel medical requests.
• Extra medication for travel purposes e.g. antibiotics in case of travellers' diarrhoea, acetazolamide for high altitude etc.
• Selling mosquito nets, repellents, sun screens, medical kits etc.
• Certificates for travel cancellation, freedom from infection, HIV negativity status, and letters certifying necessity of carrying needles in hand luggage etc.

Reimbursement

• Practices can either buy vaccines directly from vaccine manufacturers and personally administer to patients or they can prescribe via FP10 or personally administer and claim reimbursement through submission of the FP10.

• High-volume, personally administered vaccines can be claimed back through an FP34 appendix form
  • Applies to the following vaccines only:
    • Influenza
    • Typhoid
    • Hepatitis A
    • Hepatitis B
    • Pneumococcal
    • Meningococcal

• The cost of the vaccine, VAT, administration charges etc. can be claimed back to generate a profit, though a discount is applied based on the volume claimed.

National Health Service. High volume vaccine forms (FP34D / PD appendix form). Available at: www.nhsbsa.nhs.uk/PrescriptionServices/933.aspx accessed May 2014
A patient is off on a gap year, travelling to a number of different countries (some with a high prevalence of Hepatitis B).

Risk assessment suggests he should have Hepatitis B vaccination.

He has already had a full course of Hepatitis A vaccination.

Questions:

1. Can you charge the patient for the Hepatitis B course?
2. Can you give the Hepatitis B course on the NHS and claim reimbursement?
3. Can you give a combined hepatitis A&B course and claim reimbursement?
• A patient is travelling to Ghana to undertake volunteer work in a school
• Risk assessment suggests she should have Hepatitis B vaccination.
• She also needs a full course of Hepatitis A, Yellow Fever & anti-malarials
• Questions:
  1. Which of the above vaccinations/prophylaxis would she need to pay for herself?
  2. Which could be reimbursed?
Information websites

- BMA: Focus on vaccines and immunisations
  http://bma.org.uk/practical-support-at-work/gp-practices/focus-vaccinations

- National Travel Health Network and Centre (NaTHNaC)
  http://www.nathnac.org/

- TRAVAX: The A to Z of Healthy Travel
  http://www.travax.nhs.uk/

- Health Protection Agency (HPA)
  http://www.hpa.org.uk/

- Health Protection Scotland
  http://www.hps.scot.nhs.uk/
Prescribing Information

Hepatitis B (rDNA) vaccine adsorbed (HBV)

Prescribing Information - Please refer to SPC before prescribing.
Enferix B, Hepatitis B (rDNA) vaccine adsorbed (HBV) Uses: Active immunisation against hepatitis B virus infection. Dosage and administration: For i.m. use. Adults and children 16 years and above: 20 micrograms (1 ml). Neonates and children 15 years and under: 10 micrograms (0.5 ml). Series of 3 injections required for primary immunisation; doses at 0, 1 and 6 months or accelerated schedule 0, 1 and 2 months with a fourth dose at 12 months. For more rapid protection in patients 18 years and above, exceptional schedule of 0, 7 and 21 days with a fourth dose at 12 months. Booster dose only if official vaccination programmes require. Children from 11 up to and including 15 years: 20 micrograms (1 ml) can be used, doses at 0, 6 months (protection may not occur until after the second dose). Renal insufficiency including haemodialysis (patients up to 15 years of age): 10 microgram (0.5ml) at 0, 1, 2 and 12 months or 0, 1, 6 months; Renal insufficiency including haemodialysis (patients 16 years and above): 40 micrograms (2x 20 micrograms) at 0, 1, 2 and 6 months. Contra-indications: Hypersensitivity to any component of the vaccine, hypersensitivity after previous Enferix B administration, severe febrile illness. Precautions: Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Additional doses may be required for those who do not respond or have sub-optimal response. Potential risk of anaphylaxis and need for respiratory monitoring in very premature infants (born 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. Vaccine should not be administered in the buttock or intradermally since this may result in a lower immune response and should under no circumstances be administered intravenously. Exceptionally the vaccine may be administered subcutaneously in patients with thrombocytopenia or bleeding disorders. Pregnancy and lactation: used during pregnancy only when clearly needed, and the possible advantages outweigh the possible risks for the foetus. No contraindication in lactation has been established. Adverse reactions: See SPC for full details. Very common: pain and redness at injection site, fatigue, irritability, headaches (children). Common: Drowsiness, headache (adults). Gastrointestinal symptoms (such as nausea, vomiting, diarrhoea, abdominal pain), appetite lost, fever; 37.50C; malaise, swelling at injection site, injection site reactions (such as induration). Uncommon: Dizziness, myalgia, influenza-like illness. Rare: Lymphadenopathy, paraesthesia, urticaria, pruritus, rash, atrialgia. Post marketing surveillance: Thrombocytopenia, encephalitis, encephalopathy, convulsions, paralysis, neunitis (including Guillain-Barré syndrome, optic neuritis and multiple sclerosis) neuropathy, hypoesthesia, anaphylaxis, anaphylactic shock, anaphylactic reactions and mimicking serum sickness. Use in pregnancy: Category: POM Presentation and basic NHS cost: 1ml pre-filled syringe: 1, £12.99; 10, £129.92. 1ml vial: 1, £12.34; 10, £123.41. 0.5ml pre-filled syringe: 1, £9.67. MA number: 1059/2016-6. MA holder SmithKline Beecham Ltd. Trading as: GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. Further information is available at: Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontact@gsk.com. Freephone 0800 221 441. Enferix B is a registered trademark of the GlaxoSmithKline group of companies. Date of preparation: November 2013 UK/ENG/0001/12(1)

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.
Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)

Refer to Summary of Product Characteristics (SPC) before prescribing. *Twinrix Adult* and *Twinrix Paediatric*. Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed). **Uses**: Active immunisation against hepatitis A and B virus infection. **Dosage and administration**: Three doses (at 0, 1 and 6 months). When necessary due to timing of travel, for more rapid protection in adults (18 years and above), use 0, 7 and 21 days schedule; fourth dose at 12 months. **Adults and adolescents 16 years and above**: 1 ml (720 ELISA HA/20 µg HBsAg) i.m. (deltoid); **Children 1 - 15 years**: 0.5 ml (360 ELISA HA/10 µg HBsAg) i.m. (deltoid, or anterolateral thigh in infants). **Contra-indications**: Hypersensitivity to any components, neomycin or hepatitis A or B vaccines. Acute severe febrile illness. **Precautions**: Not recommended for post-exposure prophylaxis. In haemodialysis patients and persons with an impaired immune system, anticipated immune response may not be achieved after the primary immunisation course and may therefore require additional doses of vaccine. Nevertheless, these patients may fail to demonstrate an adequate response. Consider serological testing of subjects at risk of not achieving seroprotection following a complete course of *Twinrix* Adult. Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event. Avoid intradermal injection or intramuscular administration into gluteal muscle due to suboptimal response. Do not administer intravascularly under any circumstances. Subcutaneous administration may be considered for those with bleeding disorders. A protective immune response may not be elicited in all vaccinees. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic movements during recovery. It is important that procedures are in place to avoid injury from faints. **Interactions**: For information on the concomitant use of *Twinrix Paediatric/Adult* with other vaccines please refer to the SPC. Use different injection sites if administering *Twinrix* Adult with other vaccines. **Pregnancy**: Only when clear risk of hepatitis B infection. **Lactation**: Caution in breast feeding. **Adverse reactions**: See SPC for full details. *Twinrix Adult* – Very common: headache, pain and redness at injection site, fatigue. Common: gastrointestinal symptoms, diarrhoea, nausea, swelling at the injection site, injection site reactions (including haematoma, pruritus, bruising), malaise. Uncommon: dizziness, vomiting, abdominal pain, myalgia, URTI, fever. Rare: lymphadenopathy, hypoesthesia, paraesthesia, rash, pruritus, arthralgia, decreased appetite, hypotension, influenza-like illness, chills. Very rare: urticaria. *Twinrix Paediatric* – Very common: pain, redness at injection site. Common: swelling, injection site reactions, drowsiness, headache, GI symptoms, nausea, appetite loss, fatigue, malaise, fever, irritability. Uncommon: diarrhoea, vomiting, abdominal pain, rash. Rare: lymphadenopathy, dizziness, urticaria. Post-marketing, the following have been reported with *Twinrix* or GSK monovalent HA or HB vaccines: thrombocytopenia, thrombocytopenic purpura, encephalitis, encephalopathy, neuritis, neuropathy, paralysis, convulsions, angioneurotic oedema, lichen planus, erythema multiforme, arthritis, muscular weakness, meningitis, vasculitis, anaphylaxis, allergic reactions including anaphylactoid reactions and mimicking serum sickness, abnormal liver function tests, multiple sclerosis, myelitis, facial palsy, polynuertis such as Guillain-Barré syndrome (with ascending paralysis), optic neuritis, immediate injection site pain, stinging and burning sensation. **Legal category**: POM Presentation and basic NHS cost: *Twinrix Adult* pre-filled 1.0ml syringe. 1, £33.31; 10, £333.13. *Twinrix Adult* 1.0ml vial. 1, £26.44. *Twinrix Paediatric* pre-filled 0.5ml syringe. 1, £20.79. **MA number**: EU/1/96/020/001-009, EU/1/97/029/001-010. **MA holder**: GlaxoSmithKline Biologicals s.a, Rue de l’Institut 89 1330 Rixensart, Belgium. For the UK, further information is available from Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221 441. For Ireland, please contact 1800 244 255. *Twinrix* is a registered trademark of the GlaxoSmithKline group of companies. **Date of preparation**: April 2014. UK/THWI/0003/12(2)

**Adverse events should be reported.** For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.

May 2014 UK/TH/0138/13c(1)
Prescribing Information

Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)

Prescribing Information - Refer to SPC before prescribing.

AmBirix® (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed). Uses: Immunisation against hepatitis A and hepatitis B infection from 1 year up to and including 15 years of age. Hepatitis B protection may not occur until after second dose. Use only when relatively low risk of hepatitis B infection during course. Completion of course should be assured. Dosage and administration: 1ml (720 ELISA HA/20 μg HBsAg) by intramuscular injection at the elected date and a second dose six to 12 months after the first dose. Recommendations for boosting AmBirix: same as for monovalent hepatitis A or B vaccines.

Contraindications: Hypersensitivity to any component or neomycin or hypersensitivity after previous administration of hepatitis A and/or hepatitis B vaccines. Acute severe febrile illness. Precautions: Not recommended for postexposure prophylaxis. Rare anaphylactic reactions. Two-dose course should be completed prior to start of sexual activity. Do not administer intravascularly. Avoid gluteal or intradermal injection. Adequate response may not be achieved in immunocompromised patients. If rapid protection against hepatitis B is required, use three-dose regimen of combined (360 ELISA units HA/10μg HBsAg). Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic clonic movements during recovery. It is important that procedures are in place to avoid injury from faints. Interactions: No data on concomitant administration with specific hepatitis A or hepatitis B immunoglobulin. Satisfactory antibodies titres seen when administered concomitantly with DTPa-IPV+Hib or MMV vaccines in second year of life. Concomitant administration with other vaccines not recommended unless absolutely necessary. Use different injection sites, preferably different limbs, if administering AmBirix with other vaccines. Fertility, pregnancy and lactation: No fertility data are available. AmBirix can be used during pregnancy only when clearly needed, and the possible advantages outweigh the potential risks for the foetus. AmBirix should only be used during breast-feeding when the possible advantages outweigh the potential risks. Adverse Reactions: See SPC for full details. Very common: headache, appetite loss, pain/redness at injection site, fatigue and irritability. Common: drowsiness, gastrointestinal symptoms, swelling at injection site, fever. Post-marketing reactions reported following vaccination with AmBirix are: allergic reactions including anaphylaxis and anaphylactoid reactions, syncope or vasovagal responses to injection, localised hypoesthesia. The following adverse reactions were reported during clinical trials with GlaxoSmithKline’s other combined hepatitis A and hepatitis B vaccines (given as a 3 or 4 dose schedule): Common: diarrhoea, nausea, malaise, injection site reaction. Uncommon: upper respiratory tract infection, dizziness, vomiting, abdominal pain, myalgia. Rare: lymphadenopathy, paraesthesia, hypotension, pruritus, rash, arthralgia, chills, influenza like illness. Very rare: urticaria. Following widespread use of GlaxoSmithKline’s combined hepatitis A and hepatitis B vaccines or the monovalent hep A and/or hepatitis B vaccines, the following adverse reactions have additionally been reported: meningitis, thrombocytopenia, thrombocytopenic purpura, allergic reactions including mimicking serum sickness, angioneuritic oedema, multiple sclerosis, myelitis, facial palsy, polyneuritis such as Guillain-Barré syndrome (with ascending paralysis), encephalitis, encephalopathy, neuritis, optic neuritis, neuropathy, convulsions, paralysis, vasculitis, abnormal liver function tests, erythema multiforme, lichen planus, arthritis, muscular weakness, immediate injection site pain, stinging and burning sensation. Legal category: POM. Presentation and basic NHS cost: AmBirix pre-filled 1.0ml syringe. 1 unit, £31.18. MA number: EU/1/022/224/001-5. MA holder: GlaxoSmithKline Biologicals s.a., Rue de l’Institut 89, B-1330 Rixensart, Belgium. Further information available from: Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactUK@gsk.com; Freephone 0800 221 441. AmBirix is a registered trademark of the GlaxoSmithKline group of companies. Date of preparation: August 2012. UK/AMB/0008/12

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.
Hepatitis A (inactivated) vaccine (adsorbed)

Prescribing Information (refer to SPC before prescribing)

Havrix Monodose® Hepatitis A (inactivated) vaccine (adsorbed). **Uses:** immunisation against hepatitis A. **Dosage and administration:** i.m. use in the deltoid region. Adults (16 years and over): 1.0 ml Havrix Monodose (1440 ELISA units/ml) 2-4 weeks before risk of exposure. A booster dose is recommended 6-12 months after first dose for more persistent immunity. Booster dose can be given at up to 36 months and it is unnecessary to restart the primary vaccination schedule if the booster is administered within 5 years of the primary vaccination. **Contra-indications:** Hypersensitivity to any component or neomycin. **Precautions:** Immunisation should be postponed in subjects suffering from acute severe febrile illness. Have adrenaline available for immediate use in case of anaphylaxis. Havrix Monodose may not prevent hepatitis A if immunisation occurs during incubation period of hepatitis A infection. Haemodialysis and immunocompromised patients may need additional doses. Syncope can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. **Interactions:** For information on the concomitant use of Havrix Monodose with other vaccines please refer to the SPC. Simultaneous administration with normal immunoglobulin may result in a lower antibody titre. Give concomitant vaccines by separate injections into different body sites. **Pregnancy and lactation:** Should be used during pregnancy only when clearly needed. Caution in breast-feeding. **Adverse reactions:** See SPC for full details. **Very common:** headache, pain and redness at the injection site, fatigue. **Common:** loss of appetite, GI symptoms, nausea, diarrhoea, fever (≥ 37.5°C), swelling, injection site reactions such as induration, malaise. Frequency unknown (cannot be estimated from available data): anaphylaxis, allergic reactions including anaphylactoid reactions and mimicking serum sickness, convulsions, Guillain Barre Syndrome, transverse myelitis, neuralgic amyotrophy, vasculitis, transient increase in liver function tests, angioneurotic oedema, erythema multiforme, urticaria and arthralgia. **Legal category:** POM. **Presentation and basic NHS cost:** Havrix Monodose pre-filled 1.0 ml syringe. 1, £22.14; 10, £221.43. **MA number:** PL 10592/0037. **MA holder:** SmithKline Beecham Ltd. Trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, UB11 1BT. **Further information is available from:** Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. Havrix Monodose is a trademark of the GlaxoSmithKline group of companies. **Date of preparation:** April 2014. **UK/HAV/0001/13(1)**
Prescribing Information

Hepatitis A (inactivated) vaccine (adsorbed)

Prescribing Information (refer to SPC before prescribing)

**Havrix® Junior Monodose®** Hepatitis A (inactivated) vaccine (adsorbed).

**Uses**: immunisation against hepatitis A. **Dosage and administration**: i.m. use in the deltoid region or anterolateral thigh in young children. **Children/adolescents (1-15 years)**: 0.5 ml (720 ELISA units) Havrix® Junior Monodose® 2-4 weeks before risk of exposure. Booster dose up to 36 months after primary vaccination (for continuous protection, booster at 6-12 months). **Contra-indications**: Hypersensitivity to any component or neomycin. **Precautions**: Immunisation should be postponed in subjects suffering from acute severe febrile illness. Have adrenaline available for immediate use in case of anaphylaxis. Havrix Junior Monodose may not prevent hepatitis A if immunisation occurs during incubation period of hepatitis A infection. Haemodialysis and immunocompromised patients may need additional doses. Syncope can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic clonic movements during recovery. It is important that procedures are in place to avoid injury from faints. **Interactions**: For information on the concomitant use of Havrix Junior Monodose with other vaccines please refer to the SPC. Simultaneous administration with normal immunoglobulin may result in a lower antibody titre. Give concomitant vaccines by separate injections into different body sites. **Pregnancy and lactation**: Should be used during pregnancy only when clearly needed. Caution in breast-feeding. **Adverse reactions**: See SPC for full details. **Very Common**: Irritability, pain and redness at the injection site. **Common**: loss of appetite, headache, drowsiness, nausea, fever (≥ 37.5°C), swelling and malaise. **Frequency unknown (cannot be estimated from available data)**: Anaphylaxis, allergic reactions including anaphylactoid reactions and mimicking serum sickness, convulsions, Guillain-Barré syndrome, transverse myelitis, neuralgic amyotrophy, vasculitis, transient increase in liver function tests, angioneurotic oedema, erythema multiforme, urticaria, arthralgia. **Legal category**: POM. **Presentation and basic NHS cost**: Havrix® Junior Monodose® pre-filled 0.5 ml syringe. 1, £16.77; 10, £167.68. **MA number**: PL 10592/0080. **MA holder**: SmithKline Beecham Ltd. Trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, UB11 1BT. **Further information is available from**: Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. Havrix® Junior Monodose® is a trademark of the GlaxoSmithKline group of companies. **Date of preparation**: April 2014 UK/HAV72/0001/13(1)

Adverse events should be reported. For the UK, reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). For Ireland, adverse events should be reported directly to the IMB: Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.
Prescribing Information

Hepatitis A (inactivated) and typhoid polysaccharide vaccine (adsorbed)

Prescribing information - Refer to the Summary of Product Characteristics (SPC) before prescribing. Hepatix. Hepatitis A (inactivated) and Typhoid Polysaccharide vaccine (adsorbed). Uses: Active immunisation against hepatitis A virus infection and typhoid fever. Dosage and administration: i.m. (deltoid) use. Adults and adolescents 15 years of age and older: 1ml (containing Hepatitis A virus (HM175 strain) 1440 ELISA units and Vi polysaccharide of Salmonella typhi (Ty2 strain) 25μg) at least 2 weeks prior to exposure to typhoid and hepatitis A. For long term hepatitis A protection, booster dose of an inactivated hepatitis A vaccine is recommended any time between 6 - 12 months after single dose of Hepatix. A single dose (1ml) of Hepatix can be used as booster to hepatitis A vaccination between 6 and 12 months following primary immunisation with an inactivated hepatitis A vaccine to subjects who also require protection against typhoid fever. A single dose (1ml) Hepatix may be used to revaccinate against typhoid fever in subjects that also need to have a dose of hepatitis A vaccine. Revaccinate with typhoid Vi polysaccharide vaccine every 3 years if still at risk of typhoid fever. The vaccine should not be administered in the gluteal region and should under no circumstances be administered intravascularly. In exceptional circumstances, Hepatix may be administered subcutaneously to subjects with thrombocytopenia or bleeding disorders. Contra-indications: Hypersensitivity to any component or neomycin. Severe febrile illness. Precautions: appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine. Syncope (fainting) can occur following, or even without, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Adequate vaccine response may not be elicited in immunocompromised subjects and may require additional doses. It is not known whether Hepatix will prevent clinically apparent hepatitis A infections in subjects in the incubation period of hepatitis A at the time of vaccination. Pregnancy and lactation: Hepatix should only be used in pregnancy after careful consideration of the risk-benefit relationship and should only be used during breastfeeding when clearly needed. Adverse reactions: See SPC for full details. Very common: pain, erythema. Common: Headache, nausea, itching, fever, general aches, malaise, swelling. Very rare: allergic reactions (including anaphylaxis and anaphylactoid reactions), syncope, skin rashes. The following adverse reactions have been reported with GSK monovalent hepatitis A vaccine: Common: Loss of appetite, vomiting. Very rare: neurological manifestations including transverse myelitis, Guillain-Barre syndrome, neuralgic amyotrophy, convulsions, arthralgia, myalgia. Legal category: POM. Presentation and basic NHS cost: Hepatix pre-filled 1 ml syringe. 1, £32.08; 10, £320.76. MA number: PL 10592/0136 MA holder: SmithKline Beecham Ltd. Trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, UB11 1BT. Further information is available from: Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. Hepatix is a trademark of the GlaxoSmithKline group of companies. Date of preparation: November 2013. UK/HEP/0001/12(1)

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.
Vi polysaccharide typhoid vaccine

Refer to Summary of Product Characteristics (SPC) before prescribing

Typherix. Typhoid Polysaccharide vaccine. **Uses**: Active immunisation against typhoid fever. **Dosage and administration**: For intramuscular (i.m.) injection. **Adults and children (2 years and older)**: 0.5 ml (25µg Vi polysaccharide of *Salmonella typhi* Ty2 strain) at least 2 weeks prior to risk of exposure to typhoid fever. Subjects who remain at risk of typhoid fever should be revaccinated using a single dose of vaccine with an interval of not more than 3 years. **Contra-indications**: Hypersensitivity to any component. Postpone in acute severe febrile illness. **Precautions**: Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic reaction following administration of the vaccine. Bleeding may occur following intramuscular injection to subjects with thrombocytopenia or bleeding disorders and firm pressure should be applied to the site (without rubbing) for at least two minutes for these subjects. Patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate response may not be achieved. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from fiant. **Pregnancy and lactation**: Typherix should only be used when there is high risk of infection. **Adverse reactions**: See SPC for full details. **Clinical studies**: **Common**: headache, nausea, itching, fever, general aches, malaise. Following a second dose, there was an increased incidence of redness and soreness (>10%). **Post-marketing**: Very rare: urticaria, anaphylaxis, allergic reactions including anaphylactoid reactions. **Legal category**: POM. **Presentation and basic NHS cost**: Typherix pre-filled 0.5 ml syringe. 1, £9.93; 10, £99.32. **MA number**: PL 10592/0126. **MA holder**: SmithKline Beecham Ltd, Trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, UB11 1BT. **Further information is available from**: Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. Typherix is a trademark of the GlaxoSmithKline group of companies. **Date of Preparation**: November 2013. UK/TYP/0001/12(1)

Adverse events should be reported. For the UK, reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.
Meningococcal polysaccharide groups A, C, W135, Y vaccine

Prescribing Information - Refer to SPC before prescribing.

ACWY Vax®: Meningococcal polysaccharide groups A, C, W135, Y vaccine. After reconstitution one dose (0.5ml) contains 50 μg Neisseria meningitidis group A polysaccharide, 50 μg Neisseria meningitidis group C polysaccharide, 50 μg Neisseria meningitidis group Y polysaccharide 50 μg Neisseria meningitidis group W135 polysaccharide and 77 micromol of sodium. Uses: Active immunisation against invasive meningococcal disease caused by meningococci of groups A, C, W135, Y. Dosage and administration: Adults and children over 2 years: Single dose of 0.5ml by deep subcutaneous injection only. Contraindications: Hypersensitivity to any component of the vaccine, hypersensitivity after previous administration of ACWY Vax and severe febrile illness. Precautions: Appropriate medical treatment should always be readily available in case of anaphylactic reactions following the administration of the vaccine. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Never administer intravascularly or intradermally. May not elicit a protective immune response in subjects with impaired immune systems. Group C, W135 and Y polysaccharides are poorly immunogenic in children less than 24 months of age. Antibody response to group A polysaccharide is induced from 6 months of age but it is lower than that observed in older subjects and may be transient. Group C polysaccharide may induce immunological hyporesponsiveness to further doses of polysaccharide C or meningococcal group C conjugate vaccine however the clinical relevance of this phenomenon remains unknown. The solvent of the vaccine contains less than 1 mmol sodium (23 mg) per dose i.e. essentially "sodium-free". Pregnancy and lactation: ACWY Vax should be used during pregnancy only when clearly needed and the possible advantages outweigh the potential risk for the foetus and should only be used during breast-feeding when the possible advantages outweigh the potential risks. Adverse reactions: See SPC for full details. Very common: Headache, pain, redness and tenderness at injection site, fatigue. Common: Drowsiness, gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea), loss of appetite, fever, induration and swelling at injection site, irritability. Uncommon: Dizziness, urticaria, rash. Frequency unknown: Angioneurotic oedema, arthralgia, musculoskeletal stiffness, influenza-like symptoms, chills, allergic reactions (including anaphylactic and anaphylactoid reactions). Legal category: POM. Presentation and basic NHS cost: Vaccine for reconstitution with 1 pre-filled syringe of diluent: 1 unit, £16.73. MA number: PL 105920301. MA holder: SmithKline Beecham Ltd. Trading as: GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex UB11 1BT. Further information is available from: Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. ACWY Vax is a registered trademark of the GlaxoSmithKline group of companies. Date of preparation: November 2013. UK/MEN/0007/12(1)

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.
Prescribing Information

Meningococcal group A, C, W-135 and Y conjugate vaccine

Prescribing Information - Refer to SPC before prescribing. Nimenrix™ This medicinal product is subject to additional monitoring. Meningococcal group A, C, W-135 and Y conjugate vaccine. After reconstitution one dose (0.5 ml) contains 5 μg Neisseria meningitidis group A polysaccharide, 5 μg Neisseria meningitidis group C polysaccharide, 5 μg Neisseria meningitidis group W-135 polysaccharide and 5 μg Neisseria meningitidis group Y polysaccharide each conjugated to a total of 44 μg of tetanus toxoid carrier protein. Uses: Active immunisation of individuals from the age of 12 months and above against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135 and Y. Dosage and administration: Adults, adolescents, children, infants and toddlers over 12 months: Single dose of 0.5 ml by intramuscular injection only (preferably deltoid muscle but can be administered in anterolateral part of the thigh in children 12 to 23 months of age). Contraindications: Hypersensitivity to any component of the vaccine. Precautions: Never administer intravenously, intradermally or subcutaneously. Appropriate medical treatment should always be readily available in case of anaphylactic reactions following administration of the vaccine. Postpone vaccination in acute febrile illness. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Bleeding may occur following intramuscular administration to individuals with thrombocytopenia or any coagulation disorders. A protective immune response may not be elicited in all vaccinees especially in patients receiving immunosuppressive treatment. Safety and immunogenicity not assessed in patients with increased susceptibility to meningococcal infections due to conditions such as terminal complement deficiencies and functional asplenia and an adequate immune response may not be elicited in these patients. Pregnancy and lactation: Vaccination during pregnancy/lactation may be considered when the possible advantages outweigh the potential risks. Adverse reactions: See SPC for full details. Very common: Appetite loss, irritability, drowsiness, headache, fever, swelling, pain and redness at injection site, fatigue. Common: Gastrointestinal symptoms (including diarrhea, vomiting and nausea), injection site haematoma. Uncommon: Insomnia, crying, hypoesthesia, dizziness, pruritus, rash, myalgia, pain in extremity, malaise, injection site reaction (including induration, pruritus, warmth, anaesthesia). Legal category: POM. Presentation and basic NHS cost: Nimenrix vial for reconstitution with 0.5 ml pre-filled syringe of diluents. 1, £30.00; 10, £300.00. MA number: EU/1/12/767/001-004. MA holder: GlaxoSmithKline Biologicals S.A, Rue de l'Institut 88, B-1330 Rixensart, Belgium. For the UK, further information is available from Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221 441. For Ireland, please contact 1800 244 255. Nimenrix is a trade mark of the GlaxoSmithKline group of companies. Date of preparation: November 2013. UK/NIM/0002/13

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.
Prescribing Information

Atovaquone/proguanil

Prescribing Information – (Please refer to the SmPC before prescribing)

MALARONE® TABLETS (250mg atovaquone/100mg proguanil HCl) and MALARONE® PAEDIATRIC TABLETS (62.5mg atovaquone/25mg proguanil HCl).

Uses: Malariology: Prophylaxis of Plasmodium falciparum malaria and treatment of acute, uncomplicated P. falciparum malaria, especially where pathogen may be resistant to other anti-malarials. Malariology Paediatric: Prophylaxis for individuals 11-40kg. Treatment of acute, uncomplicated, P. falciparum malaria (children ≥ 6kg and <10kg). Dosage: Take once daily at the same time each day with food or milky drink. Malariology Paediatric tablets: crush and mix with food or milky drink if necessary. Repeat dose if vomiting occurs within 1 hour. Prophylaxis: Start 24-48 hours prior to exposure, continue during stay and for 7 days after leaving. Adults and children >40kg: 1 Malariology tablet (250/100mg) tablet daily; 31-40kg: 3 Malariology Paediatric tablets; 21-30kg: 2 Malariology Paediatric tablets daily; 11-20kg: 1 Malariology Paediatric tablet daily. Treatment: Take as a single dose for three consecutive days. Adults and children >40kg: 4 Malariology tablets (250/100mg) tablets; 31-40kg: 3 Malariology tablets; 21-30kg: 2 Malariology tablets; 11-20kg: 1 Malariology tablet. Children 9-10kg: 3 Malariology Paediatric (62.5/25 mg) tablets; 5-8kg: 2 Malariology Paediatric tablets. Contraindications: Hypersensitivity to any ingredient; creatinine clearance <30mL/min if for prophylaxis. Precautions: Repeat dose if vomiting within 1 hour of dosing. Treatment. Consider alternative therapy in acute malarial presenting with diarrhoea or vomiting: creatinine clearance <30mL/min with acute P. falciparum malaria. Use additional agents to treat P. vivax or P. ovale. May cause diarrhoea, vomiting or fatigue. Do not exceed single daily dose. Do not exceed duration of treatment. Glutaraldehyde solution is contraindicated in renal impairment. May cause vertigo, headache, dizziness, nausea, vomiting, diarrhoea, abdominal pain.

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. For Ireland, adverse events should be reported directly to the IMB; Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 in the UK or 1800 244 255 in Ireland.