World leaders in Meningococcal Vaccination^

PRESENTS

MENVEO
Meningococcal Group A,C,W135 & Y Conjugate Vaccine Ph. Eur.

High efficacy* with a clinically acceptable safety profile[1]	**Robust immune response** across age groups (>2 years) against all four serogroups[1,2]
~10 years of global real world experience[3]	**Approved in US & EU** only MCV licensed in both regions[4,5]

Safety information:
Most common adverse events in clinical trials:
Injection site pain, erythema, induration, sleepiness, headache, irritability, malaise, eating disorder, nausea, vomiting, diarrhea, rash, myalgia, arthralgia, fever and chills.

* The efficacy of MENVEO has been inferred by measuring the production of serogroup-specific anti-capsular antibodies with bactericidal activity[6]
^ Meningococcal Vxs global IMS data

Reference : 1. S.A. Halperin et al., Vaccine 28 (2010), 7865–7872 2. Lalwani S, et al. Int J Infect Dis. 2015;38:36-42 3. GSK data on file- Sales summary- May 2019 4. ECDC factsheet about meningococcal disease, available at https://www.ecdc.europa.eu/en/meningococcal-disease/factsheet (Accessed Nov, 2019) 5. Meningococcal Vaccine Safety, available at https://www.cdc.gov/vaccinesafety/vaccines/meningococcal-vaccine.html (Accessed Nov, 2019) 6. Menveo India Prescribing information Version MNV/PI/IN/2019/03 dated 21 August 2019

For the use only of Registered Medical Practitioners or a Hospital or a Laboratory
Abbreviated Prescribing information of MENVEO (Meningococcal Group A, C, W-135 and Y Conjugate Vaccine Ph. Eur.)
ACTIVE INGREDIENT: Each reconstituted dose (0.5ml) contains: 10 µg Meningococcal group A oligosaccharide conjugated to 16.7-33.3 µg CRM197, 5 µg Meningococcal group C oligosaccharide conjugated to 7.1-12.5 µg CRM197, 5 µg Meningococcal group W-135 oligosaccharide conjugated to 3.3-8.3 µg CRM197, 5 µg Meningococcal group Y oligosaccharide conjugated to 5.6-10 µg CRM197. Therapeutic Indication: Active immunization of children (from 2 years of age), adolescents and adults to prevent invasive meningococcal disease caused by Neisseria Meningitidis groups A, C, W-135 and Y. Posology: Children (> 2 years of age), adolescents and adults: administered as a single dose (0.5 ml). Older people: Limited data in aged 56-65. No data in aged >65 years. Booster vaccination: May be given in subjects vaccinated with same, other conjugated or unconjugated polysaccharide meningococcal vaccine. Need and timing of booster dose to be based on national recommendations. Children under 2 years of age: Safety and efficacy not established. Method of Administration: Intramuscular injection, preferably in deltoid muscle. Contraindications: Hypersensitivity to any active substance, excipient or diphtheria toxoid (CRM197), or life-threatening reaction after administration of vaccine with similar components. Postpone in acute severe febrile illness. Minor infection not a contraindication. Special Warnings and Precautions: Take all precautions for prevention of allergic or other reaction. Appropriate medical treatment and supervision should be readily available in case of rare anaphylactic reaction. Anxiety-related reactions (vasovagal reactions, syncope, hyperventilation or stress-related reactions) may occur; ensure procedure to avoid injury from fainting. Should not be administered intravascularly. Not protect against serogroups of N. meningitidis not included in vaccine. May not elicit protective immune response in all vaccinees. Waning of serum bactericidal antibody titers against serogroup A seen in studies; clinical relevance unknown. If individual at risk of exposure to Men A; consider booster dose. No data on use as post-exposure prophylaxis. Vaccination in immunocompromised individuals may not result appropriate protective antibody response. Increased risk of invasive disease in individuals with familial complement deficiencies and treatments that inhibit terminal complement activation (for example, eculizumab). Evaluate risk-benefit in persons at risk of haematoma following intramuscular injection. Interaction with Other Medicinal Products and Other Forms of Interaction: Can be given concomitantly with hepatitis A and/or B, yellow fever, typhoid fever (Vi polysaccharide), Japanese encephalitis and rabies. Administer concomitant vaccines at separate injection sites (preferably contralateral) Adolescents (11-18 years of age): Can be co-administered with Tetanus, Reduced Diphtheria and Acellular Pertussis Vaccine, Adsorbed (Tdap) alone/or Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant (HPV). Lower W-135 seroresponse on administration of MENVEO one month after Tdap; clinical relevance unknown. Children (2-10 years of age): No data on concomitantly administration with other childhood vaccines. Co-administration with other vaccines not studied. Administer concomitant vaccines at separate injection sites, preferably contralateral. Effects on Ability to Drive and Use Machines: Dizziness very rarely reported, may temporarily affect ability to drive or use machines. Undesirable Effects: Clinical Trial Data: A) Subjects aged 2 - 10 years: Very common (> 1/10): sleepiness, headache, irritability, malaise, injection site pain, erythema (≤50 mm), induration (≤50 mm) Common (≥1/100 to <1/10): eating disorder, nausea, vomiting, diarrhea, rash, myalgia, arthralgia, injection site erythema (>50mm), induration (>50mm), chills, fever ≥38°C Uncommon (≥1/1,000 to <1/100): injection site pruritus B) Subjects aged 11 to 65 years: Very common (> 1/10): headache, nausea, myalgia, injection site pain, erythema (≤50 mm), induration (≤50 mm), malaise Common (≥1/100 to <1/10): rash, arthralgia, injection site erythema (>50 mm), induration (>50 mm), fever ≥38°C, chills Uncommon (≥1/1,000 to <1/100): dizziness, injection site pruritis Post-marketing experience (all age groups): hypersensitivity including anaphylaxis, tonic convulsion, febrile convulsion, syncope, vertigo, injection site cellulitis, injection site swelling, including extensive swelling of the injected limb.
Version: MEN/API/IN updated 6-Sep-2019.
Registered medical practitioners can refer company website http://india-pharma.gsk.com/en-in/products/prescribing-information/ for full Product Information.
Please report adverse events with any GSK product to the company at india.pharmacovigilance@gsk.com.
Menveo® is a registered trademark of GSK group of companies.

PN-IN-MNV-ADVT-190001 Date of Preparation: Dec 2019

For further information please contact:
GlaxoSmithKline Pharmaceuticals Ltd., Dr. Annie Besant Road, Worli, Mumbai - 400 030.

Infanrix hexa

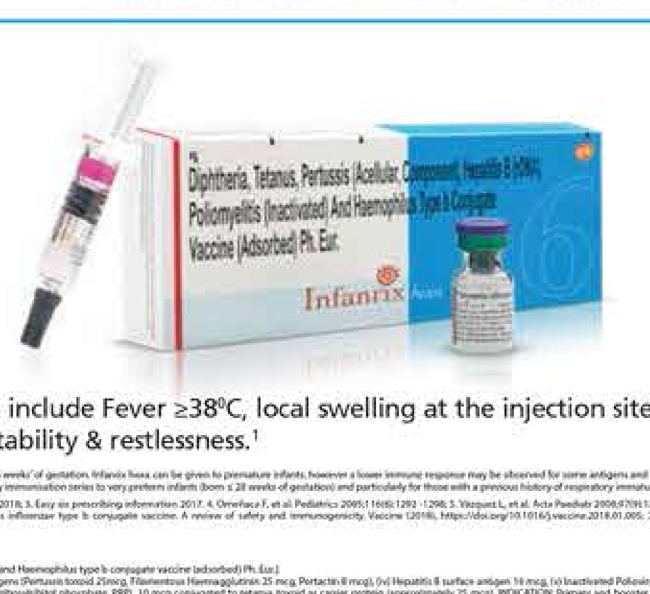
Diphtheria, Tetanus, Pertussis(Acellular, Component), Hepatitis B (rDNA), Poliomyelitis (Inactivated)And Haemophilus Type b Conjugate Vaccine(Adsorbed) Ph. Eur.

What really matters?

Efficacy | Preterms | Real-World Experience | Immune Persistence

The only 6-in-1* DTP vaccine with:[1-3]

- Up to 89% efficacy against pertussis in label[1-3]
- Multiple clinical trials specifically designed for preterm babies**,†,1-6
- The 6-in-1* vaccine with the longest follow-up of immune persistence[1-3]
- Evidence from more than 100 clinical trials and 17 years of real-world experience[1-3,7]



The very common adverse events seen with Infanrix hexa include Fever ≥38°C, local swelling at the injection site (≤50 mm), fatigue, pain, redness, appetite loss, abnormal crying, irritability & restlessness.[1]

For further information please contact:
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PCVs should be evaluated based on "Overall impact on disease" and not just on "Number of serotypes they contain"[1]

Leading International Health Authorities/Institutions have concluded comparable impact on pneumonia/ overall disease burden between Synflorix & PCV13

- World Health Organisation (WHO) position paper[2]
- Pan American Health Organization Technical Advisory Group[3]
- International Vaccine Access Center[4]
- Karolinska Institute[5]

Effective[7] yet Affordable

The very common(≥1/10) side effects with Synflorix are appetite loss, irritability, drowsiness, pain redness, swelling at injection site, fever 38° C rectally (age<2 years)[6]

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Version SYN/API/IN/2018/03 v01 dated 23-April-2019

Registered medical practitioners can refer company website http://india-pharma.gsk.com/en-in/products/prescribing-information/ for full Product Information.

Please report adverse events with any GSK product to the company at india.pharmacovigilance@gsk.com

IN/SYN/0023/18 Prepared in April 2019

For further information please contact:
GlaxoSmithKline Pharmaceuticals Ltd., Dr. Annie Besant Road, Worli, Mumbai - 400 030.

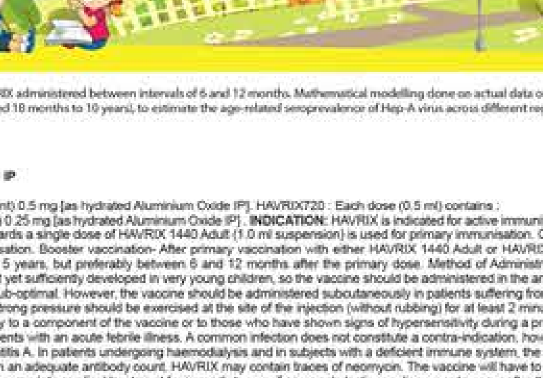
~2 out of 3 children under 10 years are at risk of Hepatitis A infection in India[1,@]

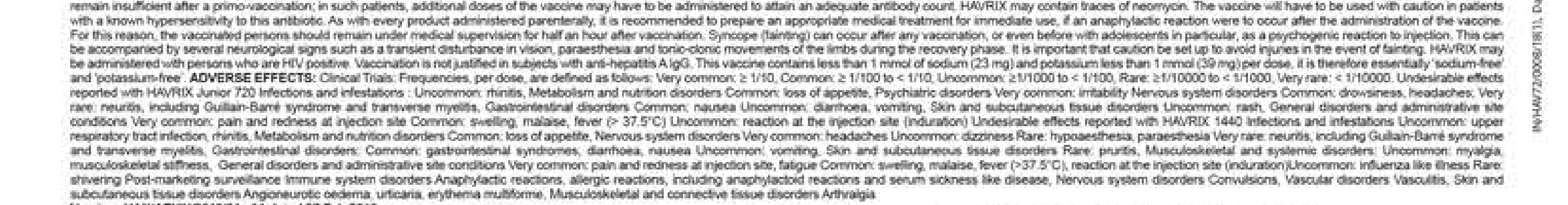
Think long term, Think Havrix

World's no. 1 Hepatitis A Vaccine
(By sales value, 2017)$

40 Years
Long term persistence of antibodies predicted by mathematical modelling*,2

Havrix
Inactivated Hepatitis A Vaccine (Adsorbed)
Think LONG TERM





$ Global IMS report, 2017 ^ Data on file as of May 2019 * Long-term persistence of antibodies against hepatitis A after 2 doses of HAVRIX administered between intervals of 6 and 12 months. Mathematical modelling done on actual data of 17 years. 90% (95% CI: 82% 95%) subjects will remain seropositive at Year 40. @ This is a prospective, multicenter, cross sectional study was conducted in 928 children (aged 18 months to 10 years), to estimate the age-related seroprevalence of Hep-A virus across different regions of India. Overall, 348 (37.5%) children were seropositive for anti-HAV antibodies
1. Arankalle et al. Vaccine development and therapy 2014;4: 7-13 2. Havrix PI, version HAX/API/IN/2019/01 v01 dated 27 Feb 2019

For the use only of Registered Medical Practitioners or a Hospital or a Laboratory
Abbreviated Prescribing information of HAVRIX 1440 (ADULT) / 720 (JUNIOR) Inactivated Hepatitis A Vaccine (Adsorbed) IP
ACTIVE INGREDIENT: HAVRIX1440: Each dose (1 ml) contains:
Hepatitis A virus antigen (HAV) [HM 175 strain, propagated in MRC5 human diploid cells] 1440 ELISA units; Aluminium (as adjuvant) 0.5 mg [as hydrated Aluminium Oxide IP]. HAVRIX720 : Each dose (0.5 ml) contains :
Hepatitis A virus antigen (HAV) [HM 175 strain, propagated in MRC5 human diploid cells] 720 ELISA units ; Aluminium (as adjuvant) 0.25 mg [as hydrated Aluminium Oxide IP] . **INDICATION:** HAVRIX is indicated for active immunisation against infections caused by hepatitis A virus (HAV). **DOSAGE AND ADMINISTRATION:** Posology Primary Vaccination- Adults from age 19 years and onwards a single dose of HAVRIX 1440 Adult (1.0 ml suspension) is used for primary immunisation. Children and adolescents from 1 year up to and including 18 years of age, a single dose of HAVRIX 720 Junior (0.5 ml suspension) is used for primary immunisation. Booster vaccination- After primary vaccination with either HAVRIX 1440 Adult or HAVRIX 720 Junior, a booster dose is recommended in order to ensure long term protection. This booster dose should be given at any time between 6 months and 5 years, but preferably between 6 and 12 months after the primary dose. Method of Administration-HAVRIX must be injected intramuscularly only. It is recommended to inject the vaccine in the deltoid region in adults and in children. The deltoid muscle is not yet sufficiently developed in very young children, so the vaccine should be administered in the anterolateral part of the thigh. The injection must not be administered in the gluteal region subcutaneously or intradermally because the antibody response might be sub-optimal. However, the vaccine should be administered subcutaneously in patients suffering from thrombocytopoenia or subject to serious haemorrhage (e.g. haemophiliacs) because bleeding could occur after intramuscular administration in such persons. Strong pressure should be exercised at the site of the injection (without rubbing) for at least 2 minutes. The vaccine may never be administered intravascularly. **CONTRA-INDICATIONS:** HAVRIX may not be administered to persons with a known hypersensitivity to a component of the vaccine or to those who have shown signs of hypersensitivity during a previous administration of HAVRIX. **SPECIAL WARNINGS and SPECIAL PRECAUTIONS:** As in the case of other vaccines, HAVRIX will not be administered to patients with an acute febrile illness. A common infection does not constitute a contra-indication, however. People may already be in the incubation period of hepatitis A at the time of vaccination. In such circumstances, it is not certain that HAVRIX will prevent hepatitis A. In patients undergoing haemodialysis and in subjects with a deficient immune system, the anti-HAV (hepatitis A virus) may remain insufficient after a primo-vaccination; in such patients, additional doses of the vaccine may have to be administered to attain an adequate antibody count. HAVRIX may contain traces of neomycin. The vaccine will have to be used with caution in patients with a known hypersensitivity to this antibiotic. As with every product administered parenterally, it is recommended to prepare an appropriate medical treatment for immediate use, if an anaphylactic reaction were to occur after the administration of the vaccine. For this reason, the vaccinated persons should remain under medical supervision for half an hour after vaccination. Syncope (fainting) can occur after any vaccination, or even before with adolescents in particular, as a psychogenic reaction to injection. This can be accompanied by several neurological signs such as a transient disturbance in vision, paraesthesia and tonic-clonic movements of the limbs during the recovery phase. It is important that caution be set up to avoid injuries in the event of fainting. HAVRIX may be administered with persons who are HIV positive. Vaccination is not justified in subjects with anti-hepatitis A IgG. This vaccine contains less than 1 mmol of sodium (23 mg) and potassium less than 1 mmol (39 mg) per dose, it is therefore essentially 'sodium-free' and 'potassium-free'. **ADVERSE EFFECTS:** Clinical Trials: Frequencies, per dose, are defined as follows: Very common: ≥ 1/10, Common: ≥ 1/100 to < 1/10, Uncommon: ≥1/1000 to < 1/100, Rare: ≥1/10000 to < 1/1000, Very rare: < 1/10000. Undesirable effects reported with HAVRIX Junior 720 Infections and infestations : Uncommon: rhinitis, Metabolism and nutrition disorders Common: loss of appetite, Psychiatric disorders Very common: irritability Nervous system disorders Common: drowsiness, headaches; Very rare: neuritis, including Guillain-Barré syndrome and transverse myelitis, Gastrointestinal disorders Common: nausea Uncommon: diarrhoea, vomiting, Skin and subcutaneous tissue disorders Uncommon: rash, General disorders and administrative site conditions Very common: pain and redness at injection site Common: swelling, malaise, fever (> 37.5°C) Uncommon: reaction at the injection site (induration) Undesirable effects reported with HAVRIX 1440 Infections and infestations Uncommon: upper respiratory tract infection, rhinitis, Metabolism and nutrition disorders Common: loss of appetite, Nervous system disorders Very common: headaches Uncommon: dizziness Rare: hypoaesthesia, paraesthesia Very rare: neuritis, including Guillain-Barré syndrome and transverse myelitis, Gastrointestinal disorders: Common: gastrointestinal syndromes, diarrhoea, nausea Uncommon: vomiting, Skin and subcutaneous tissue disorders Rare: pruritis, Musculoskeletal and systemic disorders: Uncommon: myalgia, musculoskeletal stiffness, General disorders and administrative site conditions Very common: pain and redness at injection site, fatigue Common: swelling, malaise, fever (>37.5°C), reaction at the injection site (induration)Uncommon: influenza like illness Rare: shivering Post-marketing surveillance Immune system disorders Anaphylactic reactions, allergic reactions, including anaphylactoid reactions and serum sickness like disease, Nervous system disorders Convulsions, Vascular disorders Vasculitis, Skin and subcutaneous tissue disorders Angioneurotic oedema, urticaria, erythema multiforme, Musculoskeletal and connective tissue disorders Arthralgia
Version: HAX/API/IN/2019/01 v01 dated 27 Feb 2019
Refer to full prescribing information before prescribing. Full Prescribing information available on request from GlaxoSmithKline Pharmaceuticals Limited, Dr. Annie Besant Road, Worli, Mumbai 400 030 (India).
RegRegistered medical practitioners can refer company website http://india-pharma.gsk.com/en-in/products/prescribing-information/ for full Product Information.
Please report adverse events with any GSK product to the company at india.pharmacovigilance@gsk.com

IN/HAV/72/0008/18(1), Date of prep: May 2019

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GlaxoSmithKline Pharmaceuticals Ltd., Dr. Annie Besant Road, Worli, Mumbai - 400 030.