HAVRIX® 1440 and HAVRIX® JUNIOR
Patient Information Leaflet

Read all of this leaflet carefully before you or your child are vaccinated.

HAVRIX is not for self-medication, and must be administered by a healthcare professional.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

HAVRIX has been prescribed for you or your child only. Do not pass it on to others; it may harm them even if their symptoms are the same.

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

HAVRIX® 1440 Suspension for injection

HAVRIX® JUNIOR Suspension for injection

Inactivated Hepatitis A virus (adsorbed).

WHAT HAVRIX CONTAINS:

HAVRIX 1440:

Each 1,0 mL dose of vaccine contains 1440 ELISA units of inactivated hepatitis A virus antigen.

The other ingredients are: Aluminium hydroxide, amino acids for injections, disodium phosphate, monopotassium phosphate, polysorbate 20, potassium chloride, sodium chloride and water for injections.

Residues: Traces of neomycin sulphate.

HAVRIX JUNIOR:

Each 0,5 mL dose of vaccine contains 720 ELISA units of inactivated hepatitis A virus antigen.

The other ingredients are: Aluminium hydroxide, amino acids for injections, disodium phosphate, monopotassium phosphate, polysorbate 20, potassium chloride, sodium chloride and water for injections.

Residues: Traces of neomycin sulphate.

WHAT HAVRIX IS USED FOR:

HAVRIX is a vaccine used to prevent hepatitis A disease.

The vaccine works by causing the body to make its own protection (antibodies) against this disease.

BEFORE YOU USE HAVRIX:

Do not use HAVRIX if you or your child:

- have previously had an allergic reaction to HAVRIX, or any ingredient contained in this vaccine. The active substance and other ingredients in HAVRIX are listed at the beginning of this leaflet. Signs of an allergic reaction may include itchy skin, shortness of breath and swelling of the face and tongue
- have previously had an allergic reaction to any vaccine against hepatitis A disease.

Take special care with HAVRIX if you or your child:

- have experienced any health problems after previous administration of a vaccine
- have a severe infection with a high temperature (over 38 °C). A minor infection such as a cold should not be a problem; your doctor will advise whether you or your child can still be vaccinated with HAVRIX
- are on dialysis for kidney disease
- have a poor immune system due to illness or drug treatment
- have a bleeding problem or bruise easily.

Fainting can occur following, or even before, any needle injection. Therefore tell your doctor or nurse if you/your child fainted with a previous injection.

Pregnancy and Breastfeeding:

Tell your doctor, pharmacist or other health care professional if you or your child are pregnant, may be pregnant, intend to become pregnant or are breastfeeding. Your doctor will discuss with you the possible risks and benefits of taking HAVRIX during pregnancy.

Taking other medicines with HAVRIX:

Always tell your health care professional if you are taking any other medicine. If you or your child are taking other medicines on a regular basis, including complementary or traditional medicines, the use of HAVRIX with these medicines may cause undesirable interactions. Please consult your doctor for advice.

HOW TO USE HAVRIX:

Do not share medicines prescribed for you with any other person.

Adults and children 16 years of age and older, will receive one dose (1,0 mL) of HAVRIX 1440.

Children from 1 year up to 15 years of age will receive one dose (0,5 mL) of HAVRIX JUNIOR.

An additional (booster) dose can be given at any time between 6 and 12 months after the first dose, in order to ensure long term protection.

HAVRIX is usually injected into the upper arm muscle in adults and children or into the thigh muscle in young children.

The vaccine should not be injected (deep) into the skin or into the buttocks because protection may be less.

The vaccine should never be injected into a vein.

Depending on individual circumstances and particularly if you or your child suffers from kidney disease or a poor immune system, your doctor may decide to give extra doses of vaccine to ensure protection.

For maximum protection from getting infected by Hepatitis A virus, make sure you or your child completes the full course of injections. If you or your child miss an injection, arrange another appointment as soon as you can.

POSSIBLE SIDE EFFECTS:

HAVRIX can have side effects.

Very rarely, some people can have a serious allergic reaction to the vaccine. Contact your doctor or nurse immediately if you or your child have any of the following side effects:

- itchy rash of the hands and feet
- swelling of the eyes and face
- difficulty in breathing or swallowing.

- **Very common** (these may occur with more than 1 in 10 doses of the vaccine):
  - irritability
  - headache
  - pain and redness at the injection site
  - fatigue.

- **Common** (these may occur with up to 1 in 10 doses of the vaccine):
  - loss of appetite
  - drowsiness
  - diarrhoea, nausea, vomiting
  - swelling or hard lump at the injection site
  - generally feeling unwell, fever.

- **Uncommon** (these may occur with up to 1 in 100 doses of the vaccine):
  - upper respiratory tract infection
  - runny or blocked nose
  - dizziness
  - rash
  - aching muscles, muscle stiffness not caused by exercise
  - flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills.

- **Rare** (these may occur with up to 1 per 1 000 doses of the vaccine):
  - abnormal sensation such as of burning, prickling, tickling or tingling, pins and needles

- itching
- chills.

- **Very Rare** (these may occur with up to 1 in 10 000 doses of the vaccine):
  - fits or seizures
  - narrowing or blockage of blood vessels
  - hives, red, often itchy spots which start on the limbs and sometimes on the face and the rest of the body
  - joint pain.

If any of these side effects get serious, please tell your doctor or pharmacist.

Not all side effects reported for HAVRIX are included in this leaflet. Should you or your child's general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF HAVRIX:

Store at +2 °C to +8 °C (in a refrigerator).

Store in the original packaging in order to protect from light.

Do not freeze. Discard if vaccine has been frozen.

Keep all medicines out of the reach and sight of children.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRESENTATION OF HAVRIX:

HAVRIX 1440:

- 1 mL of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber tip cap.
- 1 mL of suspension in a vial (type I glass) with a stopper (butyl rubber).

Vials are available in packs of 1 and 10, or blisters of 25. Pre-filled syringes are available in packs of 1 or 5.

HAVRIX JUNIOR:

- 0,5 mL of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber tip cap.
- 0,5 mL of suspension in a vial (type I glass) with a stopper (butyl rubber).

The tip cap and rubber plunger stopper of the pre-filled syringe and the stopper of the vial are not made with natural rubber latex.

IDENTIFICATION OF HAVRIX:

A cloudy liquid after shaking. A white deposit with a colourless liquid may form upon storage.

REGISTRATION NUMBER:

HAVRIX 1440: 29/30.1/0310

HAVRIX JUNIOR: 31/30.1/0294

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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