PART III: CONSUMER INFORMATION

HAVRIX
hepatitis A vaccine, inactivated

This leaflet is part III of a three-part "Product Monograph" published for HAVRIX (hepatitis A vaccine, inactivated) approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HAVRIX. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is used for:
HAVRIX is a vaccine used to prevent hepatitis A disease. Vaccination is the best way to protect against this disease.

HAVRIX is approved for use in persons 12 months of age and older. The first dose of the vaccine should be given at least 2 weeks prior to anticipated exposure to hepatitis A disease.

What it does:
The vaccine works by causing the body to produce its own protection (antibodies) against hepatitis A disease.

When it should not be used:
HAVRIX should not be used:

- if you or your child have a known allergy to any component of the vaccine (see What the important medicinal ingredient is and What the important nonmedicinal ingredients are sections).
- if you or your child have shown signs of a serious allergic reaction after a previous dose of this vaccine or any vaccine intended to protect against hepatitis A infection. Signs of an allergic reaction may include skin rash, shortness of breath and swelling of the face or tongue.

Immunization should be postponed if you or your child has a severe fever or infection.

What the medicinal ingredient is:
The medicinal ingredient in HAVRIX is inactivated hepatitis A virus. None of the components of the vaccine are infectious.

What the nonmedicinal ingredients are:
Aluminium (as aluminium hydroxide), amino acids for injection, disodium phosphate, monopotassium phosphate, polysorbate 20, potassium chloride, sodium chloride and water for injection. Residue from the manufacturing process: neomycin sulphate.

What dosage forms it comes in:
HAVRIX is presented as a suspension for injection.

WARNINGS AND PRECAUTIONS

BEFORE you use HAVRIX talk to your doctor or pharmacist if:

- you or your child has a severe infection with a high temperature (over 38°C).
- you or your child have any known allergies.
- you or your child is on dialysis for kidney disease.
- you or your child have a poor immune system due to illness or drug treatment.
- you are pregnant or breastfeeding.
- you or your child have a bleeding problem or bruise easily.

Please tell your doctor if you are taking or have recently taken any other medicines. You can be given other vaccines at the same time as HAVRIX, however these vaccines will be given at different injection sites.

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

INTERACTIONS WITH THIS VACCINE

HAVRIX and immune globulin (human) should be administered at separate injection sites.

When administration of other vaccines with HAVRIX is considered necessary, the vaccines must be given with different syringes and at different injection sites.

PROPER USE OF THIS VACCINE

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Usual dose:
HAVRIX is injected into the muscle in your upper arm or in the front of the thigh in young children.

Primary Immunization:
The first dose of the vaccine should protect you or your child with normal immunity from infection with hepatitis A virus within 2-4 weeks after the injection.

Booster Dose:
To ensure that you or your child is protected long-term you or your child should have a second (booster) dose of the vaccine 6 to 12 months after the first injection.

Missed Dose:
If you or your child misses a scheduled injection, talk to your doctor to arrange another visit.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all vaccines, HAVRIX can have side effects.

Side effects that may occur are the following:

Very common (more than 10% of doses):
- Irritability.
- Headache.
- Pain and redness at the injection site, fatigue.

Common (between 1% and 10% of doses):
- Loss of appetite.
- Drowsiness.
- Diarrhea, nausea, vomiting.
- Swelling or hard lump at the injection site.
- Generally feeling unwell, fever.

Uncommon (between 0.1% and 1% of doses):
- Upper respiratory tract infection, runny or blocked nose.
- Dizziness.
- Rash.
- Aching muscles, muscular stiffness not caused by exercise.
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills.

If any of the side effects get serious or if you notice any side effects not mentioned above, please tell your doctor.

This is not a complete list of side effects. For any unexpected effects while taking HAVRIX, *contact your doctor or pharmacist.*

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:
If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:
Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: 866-844-0018
By toll-free fax: 866-844-5931
By email: caefi@phac-aspc.gc.ca
At the following website:
http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

By regular mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
Ottawa, Ontario
K1A 0K9 Address Locator 6502A

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

HOW TO STORE IT

HAVRIX must be stored in a refrigerator between 2 and 8°C. **Do not freeze.** Discard if the vaccine has been frozen.

Do not use after expiration date shown on the label. The date for last use corresponds to the last day of the month mentioned.

Store all vaccines out of the reach and sight of children.

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

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.gsk.ca
or by contacting the sponsor,
GlaxoSmithKline Inc.
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1-800-387-7374

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