

HEPATYRIX[®]

(Combined inactivated hepatitis A and Vi polysaccharide typhoid vaccine)

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about HEPATYRIX vaccine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you or your child having HEPATYRIX against the expected benefits.

If you have any concerns about receiving HEPATYRIX talk to your doctor, nurse or pharmacist.

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

WHAT HEPATYRIX IS USED FOR

HEPATYRIX is a combination vaccine used to prevent hepatitis A and typhoid fever. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Hepatitis A is an infectious disease caused by a virus, which causes the liver to become inflamed (swollen). Typhoid fever is an infectious disease caused by a bacteria called *Salmonella typhi*.

Hepatitis A

Symptoms of hepatitis A usually begin 3 to 6 weeks after coming into contact with the virus. These consist of nausea (feeling sick), fever, aches and pains. After a few days the skin and/or the whites of the eyes may become yellowish (jaundice). The severity and type of symptoms can vary. Hepatitis A is often milder in young children. Most people recover completely but the illness is usually severe enough to keep adults off work for about a month.

Typhoid Fever

Symptoms of typhoid fever can begin at varying times after coming into contact with the bacteria. These consist of headache, pains in the stomach, constipation or diarrhoea and a fever that may last for one or two weeks. Patients normally get better after about four weeks, but relapses can occur.

The hepatitis A virus and *Salmonella typhi* bacteria can both be passed from person to person in food and drink, or by swimming in water contaminated by sewage. These diseases are very common in many parts of the world and the risk of infection is greatest in those areas where hygiene and sanitation are poor. Areas include Asia, India, Africa, Central and South America, the Pacific Islands, the Middle East, and the Mediterranean Basin. Vaccination is recommended for travellers to these areas, including people in the armed forces.

Hepatitis A and typhoid fever occur in New Zealand, but are not common. Some groups of people however are at a higher risk of exposure to the diseases.

Vaccination against hepatitis A is recommended for these people:

- nursing staff and healthcare workers in contact with patients in childrens wards, infectious diseases wards, emergency rooms and intensive care units
- day-care centre staff particularly where children have not been toilet trained
- staff and residents of homes for the intellectually disabled
- sewerage workers
- men who have sex with men
- people in contact with an infected person
- people with chronic liver disease or liver transplants, or people who receive certain blood products.

Vaccination against typhoid fever is recommended for laboratory workers and people in contact with an infected person, as well as travellers to countries where hygiene and sanitation are poor.

There is no specific treatment for hepatitis A. Typhoid fever can be treated with antibiotics. Vaccination is the best way to protect against infection.

HEPATYRIX will not protect against hepatitis caused by other agents or viruses (such as hepatitis B, hepatitis C or hepatitis E). If a person is already infected with hepatitis A or typhoid at the time of vaccination, HEPATYRIX may not prevent the disease in these people.

BEFORE RECEIVING HEPATYRIX

DO NOT HAVE HEPATYRIX IF :

- you have had an allergic reaction to HEPATYRIX, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include an itchy skin rash, shortness of breath and swelling of the face or tongue.

If you have had HEPATYRIX before and became unwell, tell your doctor, nurse or pharmacist before the vaccine is given.

- you have had an allergic reaction to any other hepatitis A (Havrix® or Avaxim or Vaqta) or typhoid (Typherix® or Typhim Vi or Typhvax) vaccine.
- you have a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor about this before being vaccinated.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

If you are not sure whether HEPATYRIX should be given, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you or your child.

BEFORE RECEIVING HEPATYRIX TELL YOUR DOCTOR IF:

- you are or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving HEPATYRIX during pregnancy.

- you are breast feeding. It is not known if HEPATYRIX passes into breast milk, however the vaccine is not expected to cause problems for breast-fed babies.
- you have any medical conditions, such as:
 - severe heart or lung disease
 - a liver or kidney problem
 - an immune deficiency condition (eg. HIV positive)
 - a nervous system illness
 - or a bleeding disorder;
- you have allergies to any other medicines or substances, such as dyes, foods or preservatives.
- you have received another vaccine recently, or are taking any prescription or OTC (over-the-counter) medicines. In particular mention if you are taking medicines which suppress the immune system, such as steroids or cyclosporin.

Some vaccines may be affected by other vaccines or medicines. Your doctor or pharmacist will be able to tell you what to do if HEPATYRIX is to be given with another vaccine or medicine.

HOW HEPATYRIX IS GIVEN

The doctor or nurse will give HEPATYRIX as an injection. **If you have any concerns about how this vaccine is to be given, talk to your doctor or pharmacist.**

HOW MUCH IS GIVEN

The HEPATYRIX dose is 1mL.

HOW IT IS GIVEN

HEPATYRIX will be injected into your upper arm muscle. For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should never be given intravenously.

WHEN IT IS GIVEN

HEPATYRIX is generally given as a single dose.

Your doctor will advise on the possible need for extra doses, and future booster dosing.

IF YOU MISS A DOSE

If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

WHILE YOU ARE USING HEPATYRIX

THINGS YOU MUST DO:

Keep your follow up visits with the doctor or clinic. It is important that any follow-up doses of HEPATYRIX are given at the correct times. This will ensure the best effect of the vaccine in protecting you against hepatitis A and typhoid.

THINGS TO BE CAREFUL OF:

Be careful driving or operating machinery until you know how HEPATYRIX affects you. HEPATYRIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or lightheadedness. Make sure you know how you react to HEPATYRIX before you drive a car or operate machinery, or do anything that could be dangerous if you feel dizzy or lightheaded.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well during or after a dose of HEPATYRIX.

HEPATYRIX helps protect most people from hepatitis A and typhoid, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Most of the time they are not serious; however, sometimes they can be. Some side effects may need medical treatment.

Ask your doctor or pharmacist to answer any questions you may have.

Most unwanted effects with HEPATYRIX are mild and usually clear up within a few days. These effects, generally occur around the injection site (soreness, redness, swelling). Itching, headache, fever and generally feeling unwell have also been reported, as have feeling sick and vomiting.

MILD EVENTS that have been reported after hepatitis A or typhoid vaccination.

- Tell your doctor if you notice any of the following that are troublesome or ongoing:
 - ◆ soreness, redness, swelling, itching around the injection site
 - ◆ headache, fatigue, fever
 - ◆ feeling sick or vomiting, diarrhoea
 - ◆ muscle aches and pains, painful joints

MORE SERIOUS EVENTS that have been reported rarely after hepatitis A or typhoid vaccination.

- Tell your doctor immediately if you notice any of the following:
 - ◆ feelings of numbness, weakness and/ or fatigue in limbs, tingling in fingers or toes,
 - ◆ generalised stiffness, visual changes
 - ◆ swollen glands, unusual bleeding, difficulty passing urine
 - ◆ drooping eyelids or sagging facial muscles
 - ◆ convulsions (fits)
- **As with all vaccines given by injection there is a very small risk of serious allergic reaction. This may occur days to weeks after vaccination. Contact your doctor immediately or go to the casualty department of your nearest hospital if any of the following happens:**
 - ◆ swelling of limbs, face, eyes, inside of nose, mouth or throat
 - ◆ shortness of breath, breathing or swallowing difficulties
 - ◆ hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
 - ◆ unusual tiredness or weakness that is sudden and severe

Other side effects not listed above, can also occur during or soon after a dose of HEPATYRIX. **Check with your doctor, nurse or pharmacist if you or your child have any other effects.**

Do not be alarmed by this list of possible side effects. You or your child may not experience any.

STORAGE

HEPATYRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store HEPATYRIX always:

- Keep HEPATYRIX in the refrigerator stored between +2 C and +8 C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- Keep the vaccine out of the reach of children.
- Keep HEPATYRIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over HEPATYRIX that has expired or has not been used.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE:

HEPATYRIX comes in prefilled syringes or glass vials. It is a white, slightly milky liquid.

INGREDIENTS:

The active ingredients of HEPATYRIX are 1440 ELISA units of killed hepatitis A virus and 25 micrograms of the Vi capsular polysaccharide of *Salmonella Typhi*. The vaccine is not infectious, and will not give you hepatitis A or typhoid.

Inactive ingredients in the vaccine are: aluminium hydroxide, sodium chloride, phenoxyethanol, residual amino acids for injection, formaldehyde, neomycin sulphate, polysorbate 20, trometamol and water.

HEPATYRIX does not contain any human blood or blood products, or any other substances of human origin.

FURTHER INFORMATION

HEPATYRIX is only available if prescribed by a doctor.

HEPATYRIX is available as:

Single dose vials in packs of 1 or 10

Prefilled syringes in packs of 1 or 10

DISTRIBUTOR

Distributed In New Zealand by:

GlaxoSmithKline NZ Ltd

Private Bag 106600

Downtown Auckland

Ph: (09) 367 2900

Fax (09) 367 2910

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