Package Leaflet: Information for the user

477886

Hepatyrix®
suspension for injection
Hepatitis A (inactivated) and Typhoid Polysaccharide vaccine (adsorbed).

Read all of this leaflet carefully before you start receiving this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Hepatyrix is and what it is used for
2. What you need to know before you receive Hepatyrix
3. How Hepatyrix is given
4. Possible side effects
5. How to store Hepatyrix
6. Contents of the pack and other information

1 What Hepatyrix is and what it is used for

Hepatyrix is a vaccine which helps prevent hepatitis A and typhoid fever. Hepatitis A is an infectious illness of the liver caused by a virus. Typhoid fever is an infectious illness caused by a type of bacteria called *Salmonella typhi*.

This vaccine should only be given to adults and teenagers aged 15 years and above.

How Hepatyrix works
Hepatyrix contains inactive hepatitis A virus and a very small part of the bacterium which cause typhoid fever.
- The hepatitis A virus is not alive, so this vaccine cannot cause hepatitis A infection.
- There are no live bacteria in this vaccine, so it cannot cause typhoid fever.
- When you are given the vaccine it will trigger the body's immune system to prepare itself to protect against these viruses in the future.
- Like other vaccines, Hepatyrix may not be totally effective in protecting you against hepatitis A and typhoid fever.
- Hepatyrix will not protect you if you have already caught hepatitis A or typhoid fever.
- Hepatyrix will only prevent diseases caused by Hepatitis A virus and by the bacterium *Salmonella typhi.*

Hepatitis A virus causes an infection of the liver. Typhoid fever is an infectious illness caused by a type of bacteria called *Salmonella typhi*.

Both diseases are caught and spread by eating or drinking contaminated food or water. The viruses are present in the bowel movement (motion) of infected people, even when they may have no signs of the infection. The diseases can occur in any country, but the risk is highest in places and countries where sanitation and food and water hygiene are poor.

The main signs of hepatitis A infection include a headache, fever, sickness and yellowing of the skin and eyes (jaundice). Most patients usually get better in a few weeks, but it may take some months to make a full recovery. Rarely, hepatitis A infection can also cause serious liver disease and very rarely death.

The main signs of typhoid fever include headache, pains in the stomach, constipation or diarrhoea, fever and, in some people, a rash. Patients normally get better after about four weeks, but relapses can occur. If it is not treated properly, typhoid can also be fatal.

2 What you need to know before you receive Hepatyrix

Hepatyrix should not be given:
- if you are allergic to:
  - Hepatyrix or any of the other ingredients of this vaccine (listed in section 6)
  - Neomycin, an antibiotic used to treat skin infections
- if you are allergic to any other hepatitis A vaccine or any other typhoid injection
- if you have a high temperature (fever)

Hepatyrix should not be given if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before having Hepatyrix.

Warnings and precautions
Talk to your doctor or pharmacist before you are given Hepatyrix:
- if you have a weakened immune system (for example due to HIV infection or due to medicines that suppress the immune system). You may not get the full benefits from Hepatyrix

If you are not sure if the above applies to you, talk to your doctor before having Hepatyrix.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you fainted with a previous injection.

Other medicines and Hepatyrix
Tell your doctor or pharmacist if you are taking, have recently taken, might take any other medicines, including other vaccines.
Hepatyrix can be given at the same time as most other routine vaccines. The doctor will ensure that the vaccines are injected separately and into different parts of the body. Hepatyrix must not be mixed with other vaccines in the same syringe.

In particular talk to your doctor:
- if you are to be given 'yellow fever vaccine'
- if you need an injection of immunoglobulin (antibodies obtained from blood donors)

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.

Driving and using machines
Hepatyrix may affect your ability to drive or use machines. Do not drive or use machines if you are feeling unwell.

3 How Hepatyrix is given

How your vaccine is given

Hepatyrix will be given:
- as an injection in to the muscle of the upper arm
- at least two weeks before departure, to give the immune system time to respond and start to protect you against infection.

Please tell your doctor if you have bleeding disorders or suffer from excessive bleeding. In this case, Hepatyrix may exceptionally be given deep into the skin. Since bleeding may occur while being vaccinated, firm pressure should be applied to the injection site for at least two minutes after the injection. Protection may be less if Hepatyrix is injected deep into the skin.

How much is given
- You will receive Hepatyrix as a single 1 ml dose.
- If you have not previously received a hepatitis A vaccine, one dose of Hepatyrix will protect you from hepatitis A infection for at least 1 year.
- You may be given another injection, called a "booster injection", of an inactivated hepatitis A vaccine any time between 6 and 12 months after a single dose of Hepatyrix. This is to give you long term (up to 10 years) protection against the hepatitis A virus.
- If you have already been given a hepatitis A vaccine, you may be given Hepatyrix as a booster vaccination against hepatitis A and this will also protect you against typhoid fever. A single dose of 1 ml may be given to you between 6 and 12 months after the first dose of hepatitis A vaccine.
- One dose of Hepatyrix should protect you from typhoid fever for at least 3 years. If after 3 years you remain at risk of catching typhoid fever you should arrange to see your doctor to receive a purified typhoid vaccine.

4 Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them. The following side effects may happen with this vaccine:

Allergic reactions (these may occur with up to 1 in 10,000 doses of the vaccine)
If you have an allergic reaction, see your doctor straight away. The signs may include:
- your face swelling
- low blood pressure
- difficulty breathing
- your skin going blue
- loss of consciousness

These signs usually start very soon after the injection has been given to you. See a doctor straight away if they happen after leaving the clinic.

Other side effects include:

Very Common (these may occur with more than 1 in 10 doses of the vaccine)
- pain and redness at the injection site

Common (these may occur with up to 1 in 10 doses of the vaccine)
- swelling at the injection site
- feeling generally unwell
- headache
- general aches
- a high temperature (fever)
- feeling sick
- itching

Very Rare (these may occur with up to 1 in 10,000 doses of the vaccine)
- fainting
- skin rashes
- fits (convulsions)
- joint or muscle pains
- problems with your nerves, signs may include: pins and needles, loss of feeling or numbness, problems moving your arms and legs or difficulty with walking and moving about

Other side effects have been noted with the individual hepatitis A vaccine so there is a possibility that they may also happen with Hepatyrix, these include:
- being sick (vomiting) and loss of appetite

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517, website: www.hpra.ie, e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Hepatyrix

- Keep this vaccine out of the sight and reach of children
- Store in a refrigerator (2°C -8°C)
- Do not freeze
- Protect from light
- Do not use this vaccine after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month
- Store in the original package with this leaflet
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment

6 Contents of the pack and other information

What Hepatyrix contains:
The active susbtances are:
- 25 micrograms of the Vi polysaccharide antigen (a part of the *Salmonella typhi* (Ty2 strain) bacterium that causes typhoid fever)
- 1440 ELISA units of hepatitis A viral protein.

The other ingredients are sodium chloride and water for injections

What Hepatyrix looks like and contents of the pack
Hepatyrix is presented as a white and milky suspension. It is provided in single dose (1 ml) glass pre-filled syringes. Hepatyrix is available in packs of 1 and 10 with needles or packs of 1, 10, 20, and 50 without needles, however not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24

Manufacturer:
GlaxoSmithKline Biologicals s.a., Rue de l'Institut 89, B-1330 Rixensart, Belgium

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The following information is intended for medical or healthcare professional only

The vaccine's normal appearance is a cloudy white suspension, which may sediment during storage. Shake the container well to distribute the suspension uniformly before administering the vaccine.

The vaccine should be inspected visually for extraneous particulate matter and/or discolouration prior to administration. Any unused vaccine or waste material should be disposed of safely in accordance with local regulations.

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