

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Twinrix® Adult, Suspension for injection in prefilled syringe**  
Hepatitis A (inactivated) and hepatitis B(rDNA)  
(HAB) vaccine (adsorbed)

**Read all of this leaflet carefully before you start receiving this vaccine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Twinrix® Adult is and what it is used for
2. Before you receive Twinrix® Adult
3. How Twinrix® Adult is given
4. Possible side effects
5. How to store Twinrix® Adult
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**1. WHAT TWINRIX® ADULT IS AND WHAT IT IS USED FOR**

Twinrix® Adult is a vaccine used in adults and adolescents 16 years of age and above to prevent two diseases: hepatitis A and hepatitis B. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

• **Hepatitis A:** Hepatitis A is an infectious disease, which can affect the liver. This disease is caused by the hepatitis A virus. The hepatitis A virus can be passed from person to person in food and drink, or by swimming in water contaminated by sewage. Symptoms of hepatitis A begin 3 to 6 weeks after coming into contact with the virus. These consist of nausea (feeling sick), fever and aches and pains. After a few days the whites of eyes and skin may become yellowish (jaundice). The severity and type of symptoms can vary. Young children may not develop jaundice. Most people recover completely but the illness is usually severe enough to keep people ill for about a month.

• **Hepatitis B:** Hepatitis B is caused by the hepatitis B virus. It causes the liver to become swollen (inflamed). The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit) of infected people.

Vaccination is the best way to protect against these diseases. None of the components in the vaccine are infectious.

**2. BEFORE YOU RECEIVE TWINRIX® ADULT**

**Twinrix® Adult should not be given:**

- if you have previously had any allergic reaction to Twinrix® Adult, or any ingredient contained in this vaccine. The active substances and other ingredients in Twinrix® Adult are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- if you have previously had an allergic reaction to any vaccine against hepatitis A and hepatitis B diseases.
- if you have a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.

**Take special care with Twinrix® Adult:**

- if you have experienced any health problems after previous administration of a vaccine.
- if you have a poor immune system due to illness or drug treatment.
- if you have a bleeding problem or bruise easily.
- if you have any known allergies.

A poor response to the vaccine, possibly without achieving protection against hepatitis B, is more common in older people, men rather than women, smokers, obese people, and people with long standing illnesses, or people on some type of drug treatments. Your doctor may advise you to have a blood test after you have completed the course of vaccinations to check if you have made a satisfactory response. If not, your doctor will advise you on the possible need to have extra doses.

**Using other medicines or vaccines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or have recently received any other vaccine.

**Pregnancy and breast-feeding**

Take special care with Twinrix® Adult 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 having Twinrix® Adult during pregnancy.

It is not known if Twinrix® Adult passes into breast milk, however the vaccine is not expected to cause problems in breast-fed babies.

**Important information about some of the ingredients of Twinrix® Adult**

Please tell your doctor if you have had an allergic reaction to neomycin (antibiotic).

Thiomersal is present (in trace amounts) in this product and it is possible that you may experience an allergic reaction.

**3. HOW TWINRIX® ADULT IS GIVEN**

You will receive a total of three injections over 6 months. Each injection is given on a separate visit. The first dose will be given on an elected date. The remaining two doses will be given one month, and six months after the first dose.

- First dose: at an elected date
- Second dose: 1 month later
- Third dose: 6 months after the first dose

Twinrix® Adult can also be given as a total of three doses over 1 month. This schedule may be given to adults only needing a rapid protection (e.g. overseas travellers). The first dose will be given on an elected date. The remaining 2 doses will be given 7 days and 21 days after the first dose. A fourth dose is recommended at 12 months.

- First dose: at an elected date
- Second dose: 7 days later
- Third dose: 21 days after the first dose
- Fourth dose: 12 months after the first dose

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

As indicated in Section 2, a poor response to the vaccine, possibly without achieving protection against hepatitis B, is more common in older people, men rather than women, smokers, obese people, and people with long standing illnesses, or people on some type of drug treatments. Your doctor may advise you to have a blood test after you have completed the course of vaccinations to check if you have made a satisfactory response. If not, your doctor will advise you on the possible need to have extra doses.

If you miss a scheduled injection, talk to your doctor and arrange another visit.

Make sure you finish the complete vaccination course of three injections. If not, you may not be fully protected against the diseases.

The doctor will give Twinrix® Adult as an injection into your upper arm muscle.

The vaccine should not be given (deep) into the skin or intramuscularly into the buttock because protection may be less.

The vaccine should never be given into a vein.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Twinrix® Adult can cause side effects, although not everybody gets them.

Side effects that may occur are the following:

- ♦ Very common (more than 1 per 10 doses of vaccine):
  - Pain or discomfort, redness or swelling at the injection site
  - Tiredness
- ♦ Common (less than 1 per 10 but more than 1 per 100 doses of vaccine):
  - Headache, malaise
  - Nausea
- ♦ Uncommon (less than 1 per 100 but more than 1 per 1000 doses of vaccine):
  - Fever
  - Vomiting

Additional side effects that have been reported very rarely (less than 1 per 10,000 doses of vaccine) in the days or weeks after vaccination with

Twinrix® Adult or individual hepatitis A and hepatitis B vaccines, include:

- Allergic reactions. These may be local or widespread rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness. Such reactions may occur before leaving the doctor's surgery. However, you should seek immediate treatment in any event.
- Flu-like symptoms, including chills, and muscle and joint pains
- Fits, dizziness, pins and needles, multiple sclerosis, disease of the nerves of the eye, loss of sensation in, or of the ability to move some parts of the body, severe headache with stiff neck, disruption of the normal brain functions
- Faints
- Inflammation of some blood vessels
- Feeling or being sick, loss of appetite, diarrhoea and stomach pains
- Abnormal laboratory liver test results
- Swelling of the glands
- Bleeding or bruising more easily than normal due to drop in a type of blood cell called platelets.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE TWINRIX® ADULT

Keep out of the reach and sight of children.

Do not use Twinrix® Adult after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

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

Do not freeze. Freezing destroys the vaccine.

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.

## 6. FURTHER INFORMATION

### What Twinrix® Adult contains

- The active substances are:

Hepatitis A virus (inactivated) <sup>1,2</sup>	720 ELISA Units
Hepatitis B surface antigen <sup>3,4</sup>	20 micrograms

<sup>1</sup>Produced on human diploid (MRC-5) cells

<sup>2</sup>Adsorbed on aluminium hydroxide, hydrated

0.05 milligrams Al<sup>3+</sup>

<sup>3</sup>Produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology

<sup>4</sup>Adsorbed on aluminium phosphate 0.4 milligrams Al<sup>3+</sup>

- The other ingredients in Twinrix® Adult are: phenoxyethanol, sodium chloride, water for injections.

### What Twinrix® Adult looks like and contents of the pack

Suspension for injection in prefilled syringe.

Twinrix® Adult is a white, slightly milky liquid presented in a glass prefilled syringe (1 ml).

Twinrix® Adult is available in packs of 1, 10, and 25 with or without needles.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

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## This leaflet was last approved in August 2006

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.eu.int/>.

The following information is intended for medical or healthcare professionals only:  
Upon storage, a fine white deposit with a clear colourless supernatant can be observed.

The vaccine should be well shaken to obtain a slightly opaque, white suspension and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine.

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