

## PATIENT INFORMATION

### TWINRIX® (Twin-rix)

### [Hepatitis A Inactivated & Hepatitis B (Recombinant) Vaccine]

**Read this information carefully before you receive this vaccine.**

- This information does not take the place of talking with your doctor, nurse, or other healthcare professional.
- Ask your healthcare professional for a copy of the Centers for Disease Control and Prevention's (CDC) Vaccine Information Sheets prior to immunization.

#### **What is TWINRIX and what is it used for?**

TWINRIX is a vaccine given to adults (18 years of age or older) to prevent two potentially serious diseases: hepatitis A and hepatitis B. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases. The vaccine cannot cause these diseases.

- **Hepatitis A:** The hepatitis A virus can cause a mild flu-like illness, jaundice (yellow skin or eyes), stomach pains, and dark urine. It can also result in more serious illness leading to hospitalization or, in rare cases, death.
- **Hepatitis B:** The hepatitis B virus can cause short-term (acute) illness that leads to loss of appetite, tiredness, pain in muscles, joints, and stomach, vomiting, and jaundice (yellow skin or eyes). It can also cause long-term (chronic) illness that can lead to serious consequences including liver damage (cirrhosis), liver cancer, and death.

Getting a vaccine can help protect you from these diseases. As with any vaccine, TWINRIX may not protect 100% of individuals receiving the vaccine (especially those with immune system disorders), and is not used for treatment of hepatitis A and hepatitis B.

#### **How is TWINRIX given?**

TWINRIX is given as a series of shots in the arm. There are 2 options for scheduling your doses—your doctor will help you decide which is right for you. On the standard schedule, you should receive a total of 3 shots on a 0-, 1-, and 6-month dosing schedule. In other words, the first dose is given anytime, the second dose is given 1 month after the first dose, and the third dose is given 6 months after the first dose. On the accelerated schedule, you should receive a total of 4 shots: 3 doses on a 0-, 7-, and 21–30-day schedule, followed by a booster dose at 12 months. In other words, the first dose is given anytime, the second dose is given 7 days after the first dose, the third dose is given 21–30 days after the first dose, and a booster dose is given 12 months after the first dose. Whichever dosing schedule you use, make sure you receive all your doses. If you do not, you may not be fully protected against the diseases. If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

#### **Who should not be given TWINRIX?**

**Before you receive TWINRIX, you must tell your doctor or healthcare professional if you:**

- are younger than 18 years of age
- previously had any allergic reaction to TWINRIX, or any ingredient contained in this vaccine, including yeast and the antibiotic, neomycin (see list of ingredients), or latex. Signs of a severe allergic reaction may include hives, difficulty breathing, and swelling of the throat.
- previously had an allergic reaction to any vaccine that protects against hepatitis A or hepatitis B diseases

#### **Also, tell your doctor if you:**

- are a pregnant woman or a nursing mother
- have a moderate or severe illness with or without fever. A minor illness such as a cold should not be a problem, but talk to your doctor first.
- have a bleeding problem or bruise easily
- are taking any other medicine or have recently received any other vaccine.

#### **What are the possible side effects of TWINRIX?**

Any vaccine may have some side effects but it is possible that you will have no side effects from vaccination. Side effects with TWINRIX included pain, redness, or swelling at the injection site, headache, and tiredness. Side effects seen with TWINRIX were similar to those seen with separately administered hepatitis A and hepatitis B vaccines. Other side effects that you may experience include diarrhea, nausea, fever, and vomiting. These effects usually are mild and do not last more than 48 hours following the shot. If these events continue or become severe, tell your doctor. See Adverse Reactions section of the Prescribing Information for TWINRIX for other potential side effects. As with any vaccine, rare adverse events may occur.

As with any vaccine, there is a small risk of allergic reactions. Hives, swelling of the throat, and difficulty in breathing are signs of an allergic reaction. If any of these events occur, you should seek treatment immediately. Such rare reactions can often occur before leaving the doctor's office.

If you notice any other problems following vaccination, please inform your doctor.

#### **What are the ingredients in TWINRIX?**

TWINRIX contains inactivated virus particles of hepatitis A and noninfectious proteins from hepatitis B virus. The vaccine also contains aluminum salts, amino acids, 2-phenoxyethanol (as a preservative), sodium chloride (NaCl), phosphate buffer, and polysorbate 20. Low levels of formalin, cellular proteins, neomycin sulfate (antibiotic), and yeast protein are present. A trace amount of thimerosal is also present.

The tip cap and the rubber plunger of the needleless prefilled syringe contain dry natural latex rubber.

Manufactured by **GlaxoSmithKline Biologicals**

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Research Triangle Park, NC 27709

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