

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### TWINRIX

##### combined hepatitis A (inactivated) and hepatitis B (recombinant) vaccine

Read this carefully before you receive **TWINRIX**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional and ask if there is any new information about **TWINRIX**.

##### What is **TWINRIX** used for?

**TWINRIX** ([combined hepatitis A (inactivated) and hepatitis B (recombinant) vaccine]) is a vaccine used in adults, adolescents, children and infants to prevent hepatitis A and hepatitis B diseases.

##### How does **TWINRIX** work?

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 is generally spread from person to person by putting something in the mouth that has been contaminated with hepatitis A. Hepatitis A virus can survive up to 10 months in water and on dried surfaces for 7 days. Persons with hepatitis A virus infection may not have any signs or symptoms of the disease. Older persons are more likely to have symptoms than children. If symptoms are present, they usually occur abruptly and may include fever, tiredness, loss of appetite, nausea, abdominal discomfort, dark urine, and jaundice (yellowing of the skin and eyes). Symptoms usually last less than 2 months; a few persons are ill for as long as 6 months. It takes an average of 28 days (range: 15-50 days) for symptoms to appear. During this incubation period, a person may pass hepatitis A on to others, despite having no symptoms.
- **Hepatitis B:** Hepatitis B is an infectious disease, which affects the liver. The disease is caused by the hepatitis B virus. The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit) of infected people. The hepatitis B virus is generally spread from person to person via the transfer of virus through any perforation in the skin. Hepatitis B can survive on surfaces for at least 7 days and still be capable of causing infection. If symptoms occur, they occur on the average of 12 weeks (range 9-21 weeks) after exposure to hepatitis B virus. Symptoms occur in about 70% of patients. Symptoms are more likely to occur in adults than in children. Sometimes a person with hepatitis B viral infection has no symptoms at all. The older you are the more likely you are to have symptoms. You might be infected with hepatitis B virus (and be spreading the virus) and not know it. If you have symptoms, they might include: yellow skin or yellowing of the white of your eyes (jaundice), tiredness, loss of appetite, nausea, abdominal discomfort, dark urine, clay-colored bowel movements, joint pain.

Vaccination is the best way to protect against these diseases.

It is impossible to get Hepatitis A or B diseases from the **TWINRIX** vaccine.

## What are the ingredients in TWINRIX?

Medicinal ingredients:

- inactivated hepatitis A virus [adsorbed on aluminium-oxide hydrated].
- hepatitis B virus surface antigen recombinant (S protein) [adsorbed on aluminium phosphate produced on genetically-engineered yeast cells (*Saccharomyces cerevisiae*)].

Non-medicinal ingredients:

Aluminium (as aluminium hydroxide and aluminium phosphate), sodium chloride and water for injection. Residues from the manufacturing process: amino acids for injection, formaldehyde, neomycin sulphate and polysorbate 20.

### **TWINRIX comes in the following dosage forms:**

TWINRIX is available in single dose syringes in packages of 1 and 10.

TWINRIX Junior is available in single dose syringes in packages of 1 and 10.

### **Do not use TWINRIX if:**

- you have experienced any health problems after previous administration of a vaccine.
- you have previously had any allergic reaction to TWINRIX, or any ingredient contained in this vaccine (see What the medicinal ingredient is and What the important nonmedicinal ingredients are sections). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you have previously had an allergic reaction to any vaccine against hepatitis A and hepatitis B diseases.
- 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 healthcare professional first.

### **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TWINRIX. Talk about any health conditions or problems you may have, including if:**

- you are or think you may be pregnant or if you intend to become pregnant. Your healthcare professional will discuss with you the possible risks and benefits of having TWINRIX during pregnancy.
- you are breastfeeding. It is not known if TWINRIX passes into breast milk, however the vaccine is not expected to cause problems in breast-fed babies.
- you have a poor immune system due to illness or drug treatment.
- you have a bleeding problem or bruise easily.
- you are taking any other medicine or have recently received any other vaccine.
- you have any known allergies.

### **Other warnings you should know about:**

As with other vaccines, a lower immune response 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 healthcare professional may advise you to have a blood test after you have completed the course of vaccinations to check if you have a satisfactory hepatitis B (antigen) response. If not, your healthcare professional will advise you on the possible need to have extra doses.

In these cases, your healthcare professional can determine the right time and schedule of vaccination for you.

Fainting (syncope) can occur following, or even before, any needle injection; therefore, tell the healthcare professional or nurse if you or your child fainted with a previous injection so that procedures can be put in place to avoid injury from faints.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with TWINRIX:**

TWINRIX can be given at the same time as either a combined diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, and *Haemophilus influenzae* type b vaccine or a combined measles, mumps and rubella vaccine, in the second year of life. TWINRIX Junior can be given at the same time as CERVARIX, a Human Papillomavirus vaccine.

Ask your health professional for advice about which vaccines may be given at the same time as TWINRIX or TWINRIX Junior.

TWINRIX may not have an optimal effect if used with medicines that suppress the immune system.

**How to take TWINRIX:**

**Usual dose:**

TWINRIX will be administered by your health professional as an injection into the muscle. TWINRIX can be administered at the following dosing schedules; your healthcare professional will advise you of the appropriate dosing for you:

**Pediatric Dosing Schedule:**

Vaccination Schedule	Age	Vaccine	Dosing Schedule (months)			
			0	1	6	12
<b>Standard</b> (3 dose)	1-18 years	TWINRIX Junior (0.5 mL)	X	X	X	
<b>Alternate</b> (2 dose)	1-15 years	TWINRIX (1 mL)	X		<b>6 to 12 months</b>	

**Adult Dosing Schedule:**

Vaccination Schedule	Age	Vaccine	Dosing Schedule (months)			
			0	1	6	12
<b>Standard</b> (3 dose)	Adults over 19 years of age	TWINRIX (1 mL)	X	X	X	
Vaccination Schedule	Age	Vaccine	Dosing Schedule			
			(days)			(months)
			0	7	21	12
<b>Rapid</b> (4 dose)	Adults over 19 years of age	TWINRIX (1 mL)	X	X	X	X

**Overdose:**

If you think you have received too much TWINRIX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

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

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

**What are possible side effects from using TWINRIX?**

Any vaccine can have some side effects. These are not all the possible side effects you may have when taking TWINRIX. If you experience any side effects not listed here, tell your healthcare professional.

Side effects that occurred in adults during clinical trials with the standard (3 dose) and rapid (4 dose) TWINRIX vaccination schedule were as follows:

- Very common (more than 10% of doses): Pain or discomfort, redness at the injection site, headache and tiredness.
- Common (between 1% and 10% of doses): Swelling at the injection site, diarrhea, nausea and vomiting and generally feeling unwell.
- Uncommon (between 0.1% and 1% of doses): Fever (more than 37.5°C), dizziness, upper respiratory tract infection, and aching muscles.

- Rare (between 0.01% and 0.1% of doses): Swollen glands in the neck, armpit or groin, loss of appetite, pins and needles, low blood pressure, rash and itching, muscle and joint pain and flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills.
- Very Rare (less than 0.01% of doses): Hives.

Side effects that occurred in children during clinical trials who received the standard (3 dose) TWINRIX Junior vaccination schedule were as follows:

- Very common (more than 10% of doses): Pain and redness at the injection site.
- Common (between 1% and 10% of doses): Swelling at the injection site, fever (more than 37.5°C), irritability, drowsiness, headache, loss of appetite, diarrhea, nausea and vomiting and generally feeling unwell, tiredness.
- Uncommon (between 0.1% and 1% of doses): Rash.
- Rare (between 0.01% and 0.1% of doses): Swollen glands in the neck, armpit or groin, dizziness and hives.
- Very Rare (less than 0.01% of doses): Pins and needles, loss of skin sensitivity to pain or touch, numbness of the arms and legs, low blood pressure, rash and itching, aching muscles and joint pain and flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills.

Side effects that occurred in children during clinical trials who received the alternate (2 dose) TWINRIX vaccination schedule were as follows:

- Very common (more than 10% of doses): Pain and redness at the injection site, tiredness, headache, irritability, and loss of appetite.
- Common (between 1% and 10% of doses): Swelling at the injection site, fever, drowsiness, stomach and digestive complaints.

Do not be alarmed by this list of possible side effects. It is likely that you will have no side effects from vaccination.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### **Reporting Suspected Side Effects for Vaccines**

**For the general public:** Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and GSK cannot provide medical advice.

**For healthcare professionals:** If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

**Storage:**

Store in a refrigerator (2 - 8°C).

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

Do not freeze. Freezing destroys the vaccine.

Do not use after the expiry date stated on the pack. The date for last use corresponds to the last day of the month mentioned.

Keep this vaccine out of the sight and reach of children.

**If you want more information about TWINRIX:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.gsk.ca](http://www.gsk.ca), or by calling 1-800-387-7374.

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PERSONAL VACCINATION RECORD OF TWINRIX

[Combined hepatitis A (inactivated) and hepatitis B (recombinant) vaccine]

The table on the right is provided for you to record the TWINRIX vaccine doses you have already received and to remember future doses. Keep it in a safe place with other important health records.	VACCINE	DOSE <sup>1,2</sup>	Scheduled Vaccination Date: DD-MMM-YY	Date Administered: DD-MMM-YY
	TWINRIX (combined hepatitis A & hepatitis B vaccine)	Dose 1		
		Dose 2		
		Dose 3		
		Booster <sup>3</sup>		

<sup>1</sup> For long-term protection, all scheduled doses must be received.

<sup>2</sup> Indicate Junior or Adult.

<sup>3</sup> Required only for rapid dosing.