

PART III: CONSUMER INFORMATION**TWINRIX**

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

This leaflet is part III of a three-part "Product Monograph" published when TWINRIX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TWINRIX. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE**What the vaccine is 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.

What it does:

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.

When it should not be used:

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 doctor first.

What the medicinal ingredient is:

TWINRIX contains the following active 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*)].

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What the nonmedicinal ingredients are:

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.

What dosage forms it comes in:

TWINRIX is available in single dose vials* in packages of 1, 10 and 25 and syringes in packages of 1, 10 and 25*. TWINRIX Junior is available in single dose vials in packages of 1*, 3 and 10* and syringes in packages of 1 and 10.

*Format not available in Canada

WARNINGS AND PRECAUTIONS

BEFORE you use TWINRIX talk to your doctor or pharmacist 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 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.

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 doctor 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 doctor will advise you on the possible need to have extra doses.

In these cases, your doctor 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 doctor 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.

INTERACTIONS WITH THIS VACCINE

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.

PROPER USE OF THIS VACCINE

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 doctor will advise you of the appropriate dosing for you:

Pediatric Dosing Schedule:

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

Adult Dosing Schedule:

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

Overdose:

In case of drug overdose, contact a health care practitioner, 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 doctor and arrange another visit.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Any vaccine can have some side effects.

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.

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.

This is not a complete list of side effects. For any unexpected effects while taking TWINRIX, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: 866-844-0018

By toll-free fax: 866-844-5931

By email: caefi@phac-aspc.gc.ca

At the following website:

<http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

By regular mail:

The Public Health Agency of Canada

Vaccine Safety Section

130 Colonnade Road

Ottawa, Ontario

K1A 0K9 Address Locator 6502A

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

HOW TO STORE IT

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.

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

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca> or by contacting the sponsor,

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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 received and to remember future doses. Keep it in a safe place with other important health records

VACCINE	DOSE ^{1,2}	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 ³		

¹ For long-term protection, all scheduled doses must be received.

² Indicate Junior or Adult.

³ Required only for rapid dosing.