

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR VACCINE

PATIENT MEDICATION INFORMATION

ENGERIX-B **Hepatitis B vaccine (recombinant)** **Suspension for Injection**

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

What is ENGERIX-B used for?

- ENGERIX-B is a vaccine used to prevent hepatitis B disease.

It can be expected that hepatitis D will also be prevented by immunization with ENGERIX-B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

Vaccination is the best way to protect against this disease. The vaccine does not contain live virus and cannot cause hepatitis B infection.

How does ENGERIX-B work?

The vaccine works by causing the body to produce its own protection (antibodies) against the disease.

What are the ingredients in ENGERIX-B?

Medicinal ingredients:

- Each 1.0 mL adult dose of vaccine contains 20 mcg of hepatitis B surface antigen adsorbed onto 0.5 mg of Al³⁺ as aluminium hydroxide.
- Each 0.5 mL pediatric/ adolescent dose of vaccine contains 10 mcg of hepatitis B surface antigen adsorbed onto 0.25 mg of Al³⁺ as aluminium hydroxide.

Non-medicinal ingredients: Aluminium (as aluminium hydroxide), disodium phosphate dihydrate, sodium chloride, sodium dihydrogen phosphate dihydrate, and water for injection.

ENGERIX-B comes in the following dosage forms:

- 0.5 mL single pediatric dose vials or prefilled syringes* containing 10 mcg of hepatitis B surface antigen per vial.
- 1.0 mL adult dose vials or prefilled syringes* containing 20 mcg of hepatitis B surface antigen per vial.

**Only prefilled syringes are currently available in Canada*

Do not use ENGERIX-B if:

- you or your child have previously had any allergic reaction to ENGERIX-B, or any ingredient contained in this vaccine.
- you or your child have a severe febrile infection pertaining to a fever.

In healthy subjects the presence of a minor infection is not a contraindication for vaccination.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ENGERIX-B. 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 doctor will discuss with you the possible risks and benefits of having ENGERIX-B during pregnancy.
- you are breast-feeding. It is not known if ENGERIX-B passes into breast-milk.
- you have a poor immune system due to illness or drug treatment.
- you or your child have a severe infection with a high temperature (over 38°C). In these cases, the vaccination will be postponed until you or your child have recovered. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- you or your child have a bleeding problem or bruise(s) easily.
- you or your child is taking any other medicine or have recently received any other vaccine.

Other warnings you should know about:

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, people with type 2 diabetes, or people on some type of drug treatments. Your doctor may advise you or your child to have a blood test after you have or your child has completed the course of vaccinations to check if you have or your child has made a satisfactory response or an adequate (immune) response. If not, your doctor will advise you or your child on the possible need to have extra doses.

In these cases, your doctor can determine the right time and schedule of vaccination for you or your child.

If your child has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).

Fainting 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.

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

The following may be given with ENGERIX-B:

- ENGERIX-B 10 mcg/0.5mL dose can be given at the same time as CERVARIX, a Human Papillomavirus vaccine.

How to take ENGERIX-B:

Usual dose:

The doctor will give ENGERIX-B as an injection into your upper arm muscle or into the thigh muscle of your child.

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.

Make sure you or your child finish the complete vaccination course of injections. If not, you or your child may not be fully protected against the disease.

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

For optimal protection, the recommended Standard schedule for ENGERIX-B is three doses given at 0, 1 and 6 months.

For more Accelerated protection a three dose schedule (0, 1, 2 with a booster dose at month 12) results in the development of protective anti-HBs titres by 3 months. The booster dose (at 12 months) is required to maintain prolonged protective anti-HBs titres.

Dosage and Administration Table

Vaccination Schedule	Age	Dose / Volume (mcg/ mL)	Dosing Schedule (months)				
			0	1	2	6	12
Standard (3 dose)	≥ 20 years of age	20/1.0	x	x		x	
Standard*	0-19 years of age	10/0.5	x	x		x	
Accelerated	≥ 20 years of age	20/1.0	x	x	x		x
	0-19 years of age	10/0.5	x	x	x		x
Rapid	≥ 20 years of age	20/1.0	0,7d, 21d xxx d=days				x
Alternative	11-15 years of age	20/1.0	x			x	

Overdose: Some cases of overdose have been reported. In general, the side effects reported are similar to those seen after administration of the recommended dose of ENGERIX-B.

In case of drug overdose, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you or your child misses a scheduled injection, talk to your doctor and arrange another visit.

What are possible side effects from using ENGERIX-B?

Any vaccine may have some side effects. ENGERIX-B has been widely used and the list below includes side effects that are not necessarily linked to the vaccine.

Very common (more than 1 in 10 doses of vaccine):

- irritability
- pain and redness at the injection site
- tiredness

Common (up to 1 in 10 doses of vaccine):

- loss of appetite
- headache, drowsiness
- nausea, vomiting, diarrhoea, abdominal pain
- hard lump and swelling at the injection site
- fever, generally feeling unwell

Uncommon (up to 1 in 100 doses of vaccine):

- dizziness
- aching muscles
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

Rare (up to 1 in 1000 doses of vaccine):

- paresthesia (abnormal sensation of the skin)
- rash, pruritus (itching of the skin), urticaria (hives)
- arthralgia (pain in the joints)
- abnormal liver function tests

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

These are not all the possible side effects you may feel when taking ENGERIX-B. If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional. Please also see the To help avoid side effects and Other warnings you should know about, sections.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting \(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Reporting Suspected Side Effects following immunization

For the general public: Should you experience a side effect following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and GlaxoSmithKline Canada Inc. 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 by inquiring with your local Public Health Unit or the national form available at <http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>, and send it to your local Public Health Unit.

Storage:

Store at 2 - 8°C (in a refrigerator).

Keep out of reach and sight of children.

Do not freeze. Freezing destroys the vaccine.

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

Do not use after the expiry date shown on the label.

If you want more information about ENGERIX-B:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the latest available Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website www.gsk.ca, or by calling 1-800-387-7374.

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