IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

IMOVAX® Polio

Inactivated Poliomyelitis Vaccine (Vero Cell Origin)

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

ABOUT THIS MEDICATION

What the medication is used for:

IMOVAX® Polio is a vaccine used to prevent poliomyelitis (also known as polio).

Polio is a disease caused by three types of poliovirus. People can get polio from drinking water or eating food with the polio virus in it. It is also spread from person to person. While most infections do not result in illness, severe infections can kill nerve cells. This leaves muscles permanently weak or damaged. About 1 in every 100 persons infected with the virus becomes paralyzed. Polio can paralyze muscles used for breathing, talking, eating and walking. It can also cause death.

This vaccine may be given to adults and children 2 months of age and older.

What it does:

IMOVAX® Polio causes your body to produce its own natural protection against polio viruses. After you get an IMOVAX® Polio injection, your body begins to make substances called antibodies. Antibodies help your body to fight disease. When you are exposed to polio viruses, the antibodies will help to keep you from getting sick.

When it should not be used:

IMOVAX® Polio should not be used in the following situations:

Do not give IMOVAX® Polio to anyone who has had an allergic reaction to any component of the vaccine or its container.

Do not give IMOVAX® Polio to a person who has a fever or serious illness. Wait until the person is better before giving the vaccine. A person who has had a mild illness (such as a mild cold) may have the vaccine. Ask your doctor, nurse or pharmacist for advice.

What the medicinal ingredient is:

Each 0.5 mL dose of IMOVAX® Polio contains killed purified viruses from three strains of poliomyelitis viruses

What the important nonmedicinal ingredients are:

calf serum protein, formaldehyde, neomycin, polymyxin B, streptomycin and 2-phenoxyethanol

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

What dosage forms it comes in:

A syringe containing a liquid vaccine dose of 0.5 mL for subcutaneous injection.

WARNINGS AND PRECAUTIONS

BEFORE you use IMOVAX® Polio talk to your doctor, nurse or pharmacist if you or your child have any of the following conditions:

- **Persons with diseases of the immune system or taking a medical treatment that affects the immune system**. The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **Persons who have bleeding disorders or are on blood-thinning medications.** Tell the person giving you the injection about your condition. There is a risk of excessive bleeding where you get the injection if it is not done carefully.
- **Pregnant or breast-feeding women.** It is important that you understand the risks and benefits of vaccination. IMOVAX® Polio should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.

INTERACTIONS WITH THIS MEDICATION

IMOVAX® Polio must not be mixed with other vaccines or medicinal products in the same syringe.

PROPER USE OF THIS MEDICATION

For persons 2 months of age and older, the recommended dose is 0.5 mL. The vaccine should be given under the skin (subcutaneously), preferably in the deltoid (shoulder) region.

Most people get polio vaccine when they are children. Children usually get 5 doses of IPV: at 2 months of age, a dose 2 months later, at 18 months of age and booster doses at 4 - 6 years and 14 - 16 years.

Most adults do not need polio vaccine because they were already vaccinated as children. But some adults are at higher risk and should consider polio vaccination: people travelling to areas of the world where polio is common, laboratory workers who might handle polio virus, people who may be in contact with children who received oral polio vaccine, and people in communities or groups with disease caused by the polio virus.

People who have not received at least 4 doses of any polio vaccines during their lifetime should do so using IMOVAX® Polio. People in any of the higher risk groups may need a polio vaccine booster if more than 10 years have elapsed since the last dose of their **complete** polio vaccination series.

Overdose:

Not applicable to this vaccine.

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 a dose is missed, it can be given at any time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of IMOVAX® Polio causing serious harm is extremely small. The small risks associated with IMOVAX® Polio are much less than the risks associated with getting the disease against which it protects.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving IMOVAX® Polio.

Serious side effects are extremely rare.

Side effects of this polio vaccine (IPV) are generally mild and last for only a few days after getting the needle. Some people get mild pain, swelling and redness at the spot where the needle was given.

This is not a complete list of side effects. For any unexpected effects after receiving IMOVAX® Polio, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Discard product if it has been exposed to freezing.

Do not use vaccine after expiration date.

Keep out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect that you have had a serious or unexpected event following receipt of a vaccine, you may notify the Public Health Agency of Canada:

By toll-free telephone: 613-954-5590
(1-866-844-0018)
By toll-free fax: 613-954-9874
(1-866-844-5931)
By email: caefi@phac-aspc.gc.ca
Web: 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
A/L 6502A
Ottawa, Ontario
K1A 0K9

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.sanofipasteur.ca

You may also contact the vaccine producer, Sanofi Pasteur Limited, for more information.
Telephone: 1-888-621-1146 (no charge) or 416-667-2779 (Toronto area).

Business hours: 8 a.m. to 5 p.m. Eastern Time, Monday to Friday.

This leaflet was prepared by Sanofi Pasteur Limited.

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