#### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about IPOL vaccine.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child being given IPOL against the benefits they expect it will have.

If you have any concerns about being given this vaccine, ask your doctor or pharmacist.

#### Keep this leaflet.

You may need to read it again.

### What IPOL is used for

IPOL is a vaccine used to prevent poliomyelitis ('polio').

#### How it works

IPOL works by helping the body to make its own protection against polio. After receiving the primary course (3 doses) of IPOL, the body will make antibodies. These antibodies help the body to recognise the poliovirus and prevent infection. To be protected, you or your child must be given all doses of IPOL as recommended.

Most people will produce antibodies against polio. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give you, or your child, polio.

The chance of a severe reaction to IPOL is very small, but the risks of not being vaccinated against polio may be very serious.

# Before you or your child is given IPOL

When you or your child must not be given it

### Do not have IPOL if you or your child has an allergy to:

• IPOL or any of the ingredients listed at the end of the leaflet

Symptoms of an allergic reaction may include:

- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Skin rash, itching or hives

Do not have IPOL after the expiry date printed on the pack.

Do not have IPOL if the packaging is torn or shows signs of tampering.

Talk to your doctor or pharmacist if you are not sure whether you or your child should have IPOL.

Before you or your child is given it

Tell your doctor if you or your child has ever had a lifethreatening allergic reaction to a vaccine.

#### Tell your doctor if you or your child has an illness with a high temperature or any acute illness.

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

#### Tell your doctor if you or your child has, or has had, any medical conditions, especially the following:

- Weakened immunity due to disease such as cancer or AIDS
- Weakened immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer, including radiation

Your body's response to IPOL may be reduced. If you think this may apply to you, speak to your doctor.

## Tell your doctor if you or your child has allergies to:

- polymyxin B, streptomycin or neomycin (antibiotics)
- Any other medicines
- Any other substances such as foods, preservatives or dyes

# Tell your doctor if you are pregnant or intend to become pregnant.

The risk to the foetus is not well known. Your doctor will discuss the risks and benefits of using it if you are pregnant.

### Tell your doctor if you are breast-feeding or planning to breast-feed.

Your doctor will discuss the possible risks and benefits of vaccination.

#### Taking Other Medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription.

#### Having Other vaccines

IPOL can be given at the same time as other vaccines.

### How IPOL is given

IPOL is given as an injection into the tissue below the skin of the upper arm, or into the thigh in infants and small children, although your doctor may choose to inject it elsewhere.

#### Children

#### **Primary immunisation:**

Three doses of IPOL are given 2 months apart.

In infants, IPOL can be given at the same time as their DTPa (Diphtheria-Tetanus-Pertussis) vaccine.

#### **Booster doses:**

All children who have received the first three doses of IPOL in infancy should be given another dose (a booster dose) of vaccine around 4 years of age.

#### Adults

#### **Primary Immunisation:**

If you have not been immunised against polio, then you should receive the complete primary immunisation course of 3 doses. If you have received only part of your primary immunisation course for polio, you must receive the remaining doses. It does not matter how long ago you received your last dose.

#### **Booster doses:**

A single booster dose is necessary if you are in an 'at risk' group (please see below).

If you are at ongoing risk of infection, then you need to have a single booster dose every 10 years. This applies to all adults who are at ongoing risk.

#### 'At Risk' Adults

Some adults are at greater risk of coming into contact with a live polio virus, and should be vaccinated.

These are adults who belong to one of the following groups:

- Travellers to areas or countries where polio disease is present and is a serious health problem
- Laboratory workers who handle specimens which may contain the polioviruses
- Health care workers in close contact with patients who may be excreting polioviruses

#### Side effects

### Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well after having IPOL.

All medicines (including vaccines) may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this vaccine against the benefits they expect it will have for you or your child.

# Tell your doctor if you notice any of the following and they worry you:

- Local reactions around the injection site such as redness, swelling, pain or discomfort, rash or the formation of hard lumps
- Mild fever

- Agitation, sleepiness, irritability
- Headaches
- Muscle or joint pain
- Diarrhoea
- Vomiting

These are generally mild, and short-lived.

## Tell your doctor immediately if you notice any of the following:

- Swelling of the glands in the neck, armpit or groin
- Tingling or numbness of the hands or feet

These may be serious side effects. You or your child may need urgent medical attention. Serious side effects are very rare.

#### If any of the following happens tell your doctor immediately or go to the Accident and Emergency at your nearest hospital:

- Sudden skin reactions such as rash, itching or hives
- Swelling of the head or neck, including face, lips, tongue or other parts of the body
- Shortness of breath, wheezing or difficulty breathing
- A seizure or convulsion
- Nerve pain, weakness or paralysis in the limbs, often moving to chest and face

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are very rare. Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.

### After using IPOL

#### Storage

IPOL is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store IPOL:

- Keep it where children cannot reach.
- Keep it in the original pack until it is time for it to be given.
- Keep it in the refrigerator between 2°C and 8°C. Do not freeze.

Freezing destroys the vaccine.

### **Product description**

# What it looks like and contents of the pack

IPOL is 0.5 mL of liquid vaccine in a single dose syringe.

#### What IPOL vaccine contains

Each 0.5 mL dose of IPOL contains the following ingredients:

#### **Active ingredients:**

- Poliovirus antigen Type 1, 40 D antigen units
- Poliovirus antigen Type 2, 8 D antigen units
- Poliovirus antigen Type 3, 32 D antigen units

#### Other ingredients:

- 2-phenoxyethanol
- · Formaldehyde,
- Medium 199 Hanks supplemented with polysorbate 80, and pH adjusted with hydrochloric acid or sodium hydroxide

## IPOL may also contain traces of the following:

- Polymyxin B
- Streptomycin
- Neomycin
- Bovine serum albumin

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of encephalopathy) has resulted from the administration of any vaccine product.

# Name and Address of the Sponsor:

#### Australia:

sanofi-aventis australia pty ltd 12 - 24 Talavera Road Macquarie Park NSW 2113 Australia

Tel: 1800 829 468

#### **New Zealand:**

sanofi-aventis new zealand limited Level 8, James & Wells Tower 56 Cawley St Ellerslie Auckland New Zealand

Tel: 0800 727 838 **Aust R number** 

Aust R 47217

#### Date of preparation

16 January 2013