

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this vaccine, speak to your doctor or pharmacist.

### 1. Why do I need Ipol?

Ipol is a vaccine. It is used to prevent poliomyelitis ('polio') in infants, children and adults.

For more information, see Section [1. Why do I or my child need Ipol?](#) in the full CMI.

### 2. What should I know before I am given Ipol?

Do not use if you or your child ever had an allergic reaction to Ipol or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you or your child has any other medical conditions, or take any other medicines.**

**Talk to your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Ipol?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Ipol and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is Ipol given?

Ipol is given by a doctor or nurse 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.

More instructions can be found in Section [4. How is Ipol given?](#) in the full CMI.

### 5. What should I know after I am given Ipol?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Keep an updated record of vaccinations.</li><li>• Keep follow-up appointments with your doctor or clinic.</li></ul>
<b>Looking after your vaccine</b>	Ipol is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Ipol: <ul style="list-style-type: none"><li>• keep in fridge between 2-8°C. Do not freeze.</li></ul>

For more information, see Section [5. What should I know after I am given Ipol?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include local reactions around the injection site (such as redness, swelling, pain or discomfort, rash or the formation of hard lumps), fever, agitation, sleepiness, irritability, headaches, muscle or joint pain, diarrhoea, vomiting. Serious side effects include swelling of the glands in the neck, armpit or groin, tingling or numbness of the hands or feet, sudden skin reactions such as rash, itching or hives, a seizure or convulsion or sudden-life threatening allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ipol. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ipol.**

### Where to find information in this leaflet:

- [1. Why do I need Ipol?](#)
- [2. What should I know before I am given Ipol?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Ipol given?](#)
- [5. What should I know after I am given Ipol?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why do I need Ipol?

**Ipol contains the active ingredient poliovirus (inactivated).** Ipol is a vaccine used to prevent poliomyelitis ('polio') in infant, children, and adults.

### 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 many 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.

## 2. What should I know before I am given Ipol?

### Warnings

#### Do not use Ipol if you or your child:

- Is allergic 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
- 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.

Always check the ingredients to make sure you or your child can have this vaccine.

#### Check with your doctor if you or your child:

- has weakened immunity due to disease (such as cancer or AIDS) or due to treatment with medicines such as corticosteroids or other medicines used to treat cancer, including radiation.
- has allergies to polymyxin B sulfate, streptomycin sulfate or neomycin (antibiotics), or any other medicines, foods, preservatives or dyes
- has a bleeding disorder

After vaccination, you or your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. The risk to the foetus is not well known.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Ipol must not be mixed with other vaccines or medicinal products. Ipol can be given at the same time as other vaccines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect Ipol.**

## 4. How is Ipol given?

### How much to use

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.

### When to use Ipol

#### 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

#### If you or your child missed a dose of Ipol

If you or your child missed a dose of Ipol, talk to your doctor and arrange another visit as soon as possible.

#### If you or your child received too much Ipol

Overdose is most unlikely because your doctor or nurse gives the injections. If you have any concerns, ask your doctor.

## 5. What should I know after I am given Ipol?

#### Things you should do

- Keep an updated record of vaccinations.
- Keep follow-up appointments with your doctor or clinic. It is important you and your child has follow-up doses of Ipol at the appropriate times to make sure the vaccine has the best chance of providing protection polio.

#### Call your doctor straight away if you or your child:

- does not feel well after having Ipol.

Remind any doctor you visit that you or your child had Ipol.

## Looking after your vaccine

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

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

If you or your child no longer needs to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

## 6. Are there any side effects?

All medicines including vaccines can have side effects. If you or your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Local reactions around the injection site such as redness, swelling, pain or discomfort, rash or the formation of hard lumps</li> <li>• Fever</li> <li>• Agitation, sleepiness, irritability</li> <li>• Headaches</li> <li>• Muscle or joint pain</li> <li>• Diarrhoea</li> <li>• Vomiting</li> </ul>	<p><b>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</b></p>

#### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Swelling of the glands in the neck, armpit or groin</li> <li>• Tingling or numbness of the hands or feet</li> <li>• Sudden skin reactions such as rash, itching or hives</li> <li>• A seizure or convulsion</li> <li>• sudden life-threatening allergic reaction. Symptoms include: <ul style="list-style-type: none"> <li>○ sudden signs of allergy such as rash, itching or hives on the skin</li> <li>○ swelling of the face, lips, tongue or other parts of the body</li> </ul> </li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>○ shortness of breath, wheezing or trouble breathing.</li> </ul>	

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 else that may be making you or your child feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you or your child experiences, you can report side effects as follows:

Australia: Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

By reporting side effects, you can help provide more information on the safety of this vaccine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines or stop giving any medicines to your child.**

## 7. Product details

This vaccine is only available with a doctor's prescription.

### What Ipol contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>• Poliovirus inactivated Type 1, 29D Antigen Units*</li> <li>• Poliovirus inactivated Type 2, 7D Antigen Units*</li> <li>• Poliovirus inactivated Type 3, 26D Antigen Units*</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• phenoxyethanol</li> <li>• Formaldehyde</li> <li>• Medium 199 Hanks supplemented with polysorbate 80, and pH adjusted with hydrochloric acid or sodium hydroxide</li> </ul> <p><b>Ipol may also contain traces of the following:</b></p> <ul style="list-style-type: none"> <li>• Polymyxin B sulfate</li> <li>• Streptomycin sulfate</li> <li>• Neomycin</li> <li>• Bovine serum albumin</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>• Phenylalanine</li> </ul>

\*These quantities are the same as those previously expressed when measured by a suitable method.

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.

**Do not take this vaccine if you or your child are allergic to any of these ingredients.**

### What Ipol looks like

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

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### Who distributes Ipol

#### Australia:

sanofi-aventis australia pty ltd

12 - 24 Talavera Road,

Macquarie Park, NSW 2113

Australia

Tel: 1800 818 806

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