

# PNEUMOVAX<sup>®</sup> 23

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## Consumer Medicine Information (CMI) summary

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

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### 1. Why am I or my child being given PNEUMOVAX 23?

**PNEUMOVAX 23 contains a mixture of inactive parts from 23 of the most common types of pneumococcal bacteria.** PNEUMOVAX 23 is a vaccine given to help prevent infections caused by certain types of germs or bacteria called pneumococcus (pronounced new-mo-kock-us).

For more information, see Section [1. Why am I or my child being given PNEUMOVAX 23?](#) in the full CMI.

### 2. What should I know before I or my child are given PNEUMOVAX 23?

Do not get PNEUMOVAX 23 if you or your child have ever had an allergic reaction to PNEUMOVAX 23 or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you or your child have any other medical conditions, take any other medicines or vaccines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I or my child are given PNEUMOVAX 23?](#) in the full CMI.

### **3. What if I or my child are taking other medicines or vaccines?**

Some medicines or vaccines may interfere with PNEUMOVAX 23 and affect how it works. Tell your doctor, nurse or pharmacist if you or your child are taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

For more information, see Section [3. What if I or my child are taking other medicines or vaccines?](#) in the full CMI.

### **4. How is PNEUMOVAX 23 given?**

PNEUMOVAX 23 is given as an injection by a doctor or trained nurse, either into a muscle, such as your upper arm or mid-thigh, or under the skin.

More instructions can be found in Section [4. How is PNEUMOVAX 23 given?](#) in the full CMI.

## 5. What should I know after I or my child are given PNEUMOVAX 23?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, nurse or pharmacist you visit that you or your child have been given PNEUMOVAX 23.</li></ul>
<b>Looking after your vaccine</b>	<ul style="list-style-type: none"><li>• PNEUMOVAX 23 is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store PNEUMOVAX 23, keep it in the refrigerator, do not freeze.</li></ul>

For more information, see Section [5. What should I know after I or my child are given PNEUMOVAX 23?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects are: soreness, redness, warmth, swelling or hard lump where you had the injection, fever, chills, headache, unusual tiredness or weakness, generally feeling unwell, nausea, vomiting.

Other side effects include: extensive swelling of the vaccinated limb, aching muscles, muscle tenderness or weakness, not caused by exercise, decreased ability to move limb, painful or swollen joints, tingling or numbness of the hands or feet, swollen and painful lymph glands, unusual bleeding or bruising, convulsions or fits due to fever.

Serious side effects can include signs of allergy such as skin rash, itching, pinkish, itchy swellings on the skin, also called hives, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, swelling of other parts of the body, shortness of breath, wheezing or trouble breathing.

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

# PNEUMOVAX® 23

**Pneumococcal Vaccine Polyvalent; Pneumococcal purified capsular polysaccharides**

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using PNEUMOVAX 23. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using PNEUMOVAX 23.**

**Where to find information in this leaflet:**

- [1. Why am I or my child being given PNEUMOVAX 23?](#)
- [2. What should I know before I or my child are given PNEUMOVAX 23?](#)
- [3. What if I or my child are taking other medicines or vaccines?](#)
- [4. How is PNEUMOVAX 23 given?](#)
- [5. What should I know after I or my child are given PNEUMOVAX 23?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

# 1. Why am I or my child being given PNEUMOVAX 23?

**PNEUMOVAX 23 contains a mixture of inactive parts from 23 of the most common types of pneumococcal bacteria.**

PNEUMOVAX 23 is a vaccine given to help prevent infections caused by certain types of germs or bacteria called pneumococcus (pronounced new-mo-kock-us).

PNEUMOVAX 23 helps protect against the most common types of pneumococcal bacteria.

PNEUMOVAX 23 works by causing your body to produce its own protection against pneumococcal infection. It does this by making disease-fighting substances called antibodies to fight the bacteria. The vaccine itself cannot cause the infection. If a vaccinated person comes into contact with live bacteria, the body is usually ready and produces antibodies to destroy it.

The chance of a severe reaction from PNEUMOVAX 23 is very small, but the risks from not being vaccinated may be very serious.

As with all vaccines, PNEUMOVAX 23 may not fully protect all those who get it.

**PNEUMOVAX 23 is not recommended for use in children below 2 years of age.**

It can be given to children 2 years of age and older, teenagers and adults who:

- have no spleen or a spleen that does not function properly, including sickle cell disease
- have a decreased immune system and are at increased risk of pneumococcal infection, for example, people with organ transplants, HIV or certain cancers
- have long-term diseases and are at increased risk of pneumococcal infection
- have leakage of fluid from around the brain and spinal cord

It can also be given to Aboriginal and Torres Strait Islander people over 50 years of age.

In addition, PNEUMOVAX 23 is recommended for people aged 65 years and older.

Pneumococcal infection is an important cause of death worldwide. Protection against pneumococcal infection is important because the germs or bacteria can cause serious diseases such as:

- meningitis, an infection of the brain and/or spinal cord
- pneumonia, an infection of the lungs
- a severe infection of the middle ear
- a severe infection in the blood.

Groups of people who are at increased risk of pneumococcal disease include those who have poor immune systems, such as people with organ transplants, certain cancers and HIV/AIDS. Other people who are at risk of pneumococcal disease include those with no spleen, those with long-term problems of the heart, lung, kidney or liver, diabetes mellitus, alcoholics and people aged 65 years and older, and those who smoke. The

vaccine is currently recommended in the Australian Immunisation Handbook for tobacco smokers.

Infection from pneumococcal bacteria usually occurs when you come into contact with an infected person. The infection may be spread when an infected person coughs or sneezes near another person. Apart from certain diseases, other situations that may increase the risk of infection include:

- being around groups of other children (e.g. Daycare)
- living in the same household as someone who is infected.

## **2. What should I know before I or my child are given PNEUMOVAX 23?**

### **Warnings**

**You or your child should not get PNEUMOVAX 23 if:**

- **you or your child are allergic to PNEUMOVAX 23,** or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can get this vaccine.
- **the expiry date on the pack has passed**  
If the vaccine is given after the expiry date has passed, it may not work.
- **your child is under 2 years of age**



The safety and effectiveness of PNEUMOVAX 23 in children below the age of 2 years have not been established.

If you are not sure whether you or your child should be given PNEUMOVAX 23, talk to your doctor.

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

- **are pregnant or intend to become pregnant**
- **have any medical conditions, especially the following:**
  - heart or lung problems
  - idiopathic thrombocytopenic purpura (ITP), a disease which causes unusual bleeding or bruising under the skin
  - blood problems
- **have an infection or a high temperature**

Your doctor may decide to delay you or your child's injection of PNEUMOVAX 23.
- **are currently being treated or have recently been treated with radiotherapy or chemotherapy**

Your doctor may decide to delay you or your child's injection of PNEUMOVAX 23.
- **have been vaccinated with a pneumococcal vaccine before**

Routine revaccination of people with normal immune systems previously vaccinated with PNEUMOVAX 23 is not recommended.

However, revaccination is recommended for people at highest risk of serious pneumococcal infection, at different times. Your doctor will decide if and when you or your child need another injection of PNEUMOVAX 23.

- **have any allergies to any other medicines or vaccines**, or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you or your child are given an injection of PNEUMOVAX 23.

After being given PNEUMOVAX 23, you 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.

It is not known whether the vaccine is harmful to an unborn baby when given to a pregnant woman. Your doctor will give you PNEUMOVAX 23 only if it is clearly needed.

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

It is not known whether PNEUMOVAX 23 passes into breast milk. Your doctor will discuss the possible risks and benefits of you being given PNEUMOVAX 23 while breast-feeding.

### **3. What if I or my child are taking other medicines or vaccines?**

**Tell your doctor, nurse or pharmacist if you or your child are taking any other medicines or vaccines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.**

PNEUMOVAX 23 may not work as well as it should if you or your child are taking or receiving medicines that decrease the immune system, such as corticosteroids (e.g. prednisone), cyclosporin, or chemotherapy.

#### **Getting PNEUMOVAX 23 with other vaccines**

PNEUMOVAX 23 should not be given at the same time as ZOSTAVAX®. For more information about these vaccines, talk to your doctor or health care provider, because it may be better to get these vaccines at least 4 weeks apart.

**Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vaccines, vitamins or supplements you or your child are taking and if these affect PNEUMOVAX 23.**

## **4. How is PNEUMOVAX 23 given?**

### **How much is given**

Your doctor will decide on the dose of PNEUMOVAX 23 that you or your child will be given.

The usual dose of PNEUMOVAX 23 is 0.5 mL. The dose of the vaccine is the same for everyone.

Usually only one injection is needed to help protect against pneumococcal disease. However, if you or your child are at increased risk of serious pneumococcal infection, you may need to have a second injection. Your doctor will decide if and when you or your child need a second injection of PNEUMOVAX 23.

### **How is PNEUMOVAX 23 given**

- PNEUMOVAX 23 is given as an injection by a doctor or trained nurse, either into a muscle, such as you or your child's upper arm or mid-thigh, or under the skin. The vaccine should not be injected directly into veins (intravenously).

## **5. What should I know after I or my child are given PNEUMOVAX 23?**

### **Things you should do**

Remind any doctor, nurse or pharmacist you visit that you or your child have been given PNEUMOVAX 23.

## Looking after your vaccine

PNEUMOVAX 23 is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store PNEUMOVAX 23:

- Keep it where children cannot reach it.
- Keep it in the refrigerator, but not in the door compartment.
- Do not put PNEUMOVAX 23 in the freezer, as freezing destroys the vaccine.
- Keep the injection in the original pack until it is time for it to be given.

## Getting rid of any unwanted medicine

It is unlikely that you will be asked to dispose PNEUMOVAX 23. However, if you no longer need this vaccine or it is out of date, take it to any pharmacy for safe disposal.

**Do not get 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 do 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, nurse or pharmacist if you have any further questions about side effects.

**Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● soreness, redness, warmth, swelling or hard lump where you had the injection. These may be more common and intense after a second injection than after the first injection.</li> <li>● fever</li> <li>● chills</li> <li>● headache</li> <li>● unusual tiredness or weakness</li> <li>● generally feeling unwell</li> <li>● nausea, vomiting</li> </ul> <p>These are usually mild side effects of PNEUMOVAX 23. They usually improve or disappear within a few days.</p>	<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>● extensive swelling of the vaccinated limb</li><li>● aching muscles, muscle tenderness or weakness, not caused by exercise</li><li>● decreased ability to move limb</li><li>● painful or swollen joints</li><li>● tingling or numbness of the hands or feet</li><li>● swollen and painful lymph glands</li><li>● unusual bleeding or bruising</li><li>● convulsions or fits due to fever</li></ul> <p>These may be serious side effects. You or your child may need urgent medical attention. These side effects are rare.</p>	<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>

# Allergic Reaction

Allergic Reaction	What to do
<p>As with all vaccines given by injection, there is a very small risk of a serious allergic reaction or other serious conditions.</p> <ul style="list-style-type: none"> <li>● skin rash, itching</li> <li>● pinkish, itchy swellings on the skin, also called hives</li> <li>● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>● swelling of other parts of the body</li> <li>● shortness of breath, wheezing or trouble breathing</li> </ul> <p>These are serious side effects. If you or your child have them, you or your child may have had a serious allergic reaction or other serious reaction to PNEUMOVAX 23. You</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these allergic reactions.</b></p>



<b>Allergic Reaction</b>	<b>What to do</b>
or your child may need urgent medical attention or hospitalisation.	

Most of these side effects occur within the first few hours of vaccination but some may occur later.

Other side effects not listed above may also occur in some patients.

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you or your child feel unwell.**

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

## **Reporting side effects**

After you have received medical advice for any side effects you or your child experience, you can report side effects to the 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.

## **7. Product details**

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

# What PNEUMOVAX 23 contains

<b>Active ingredient (main ingredient)</b>	Inactive parts from 23 of the most common types of pneumococcal bacteria.
<b>Other ingredients (inactive ingredients)</b>	phenol sodium chloride water for injections

PNEUMOVAX 23 is made without any human blood or blood products.

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 bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

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

## What PNEUMOVAX 23 looks like

PNEUMOVAX 23 comes in glass vials or pre-filled syringes.

Vials - AUST R 10507

Pre-filled syringes - AUST R 222235

Not all presentations and pack sizes may be supplied.

The tip cap and plunger stopper of the pre-filled syringe are not made with natural rubber latex.

The vial stopper is not made with natural rubber latex.

## **Who sponsors PNEUMOVAX 23**

Merck Sharp & Dohme (Australia) Pty Limited

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