PRIORIX

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor or pharmacist.

1. Why am I being given PRIORIX?

PRIORIX is a vaccine used to prevent three diseases caused by viruses; measles, mumps and rubella (German measles) (MMR). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

For more information, see Section 1. Why am I being given PRIORIX? in the full CMI.

2. What should I know before I am given PRIORIX?

Do not receive this vaccine if you have ever had an allergic reaction to PRIORIX or any of the ingredients listed at the end of the CMI.

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

For more information, see Section 2. What should I know before I use PRIORIX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRIORIX 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 PRIORIX given?

- The doctor or nurse will give PRIORIX as an injection. PRIORIX is generally injected into the upper leg muscle in infants under 12 months of age. In children over 12 months of age, older children and adults, the injection may be given in the upper arm muscle.
- PRIORIX is generally given as a single 0.5 mL dose. The same dose is used for children and adults.

More instructions can be found in Section 4. How is PRIORIX given? in the full CMI.

5. What should I know when I am given PRIORIX?

Things you should do	• Before receiving PRIORIX, tell your doctor if you/your child have any medical problems such as tuberculosis, a family history of convulsions or allergies, a bleeding disorder, a weakened immune system, have received a blood or plasma transfusion or have been given an immunoglobulin in the last 3 months, are breast-feeding or pregnant, or have received another vaccine within the last month or have shown bleeding or bruising after previous MMR vaccination. • Remind any doctor, dentist or pharmacist you visit that you have been given PRIORIX.
Things you should not do	• Do not receive PRIORIX if you have an allergic reaction to any ingredient in the vaccine, or to eggs, if you have become unwell after MMR vaccination, you have a severe infection, or lowered immunity.
Looking after your vaccine	• PRIORIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. If you need to store PRIORIX always store it in the refrigerator between 2°C and 8°C in the original package to protect it from light, and out of reach of children.

For more information, see Section 5. What should I know when I am given PRIORIX? in the full CMI.

6. Are there any side effects?

The following are very common or common side effects observed with PRIORIX include pain and redness at the injection site, fever, rash, allergic reactions, ear and throat infection, bronchitis, cough, diarrheoa, vomiting, headache. Serious side effects such as allergic reaction, seizures, meningitis, and infection cause temporary loss of control of bodily movements have also been observed. If you experience these serious side effects, contact your doctor immediately or go to the emergency department of the nearest hospital.

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.

PRIORIX

Active ingredients: *Measles-Mumps-Rubella vaccine live*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I being given PRIORIX?
2. What should I know before I am given PRIORIX?
3. What if I am taking other medicines?
4. How is PRIORIX given?
5. What should I know while being given PRIORIX?
6. Are there any side effects?
7. Product details

1. Why am I being given PRIORIX?

PRIORIX is a vaccine used to prevent three diseases, measles, mumps and rubella (German measles). The vaccine is sometimes called MMR vaccine.

Measles, mumps and rubella are all infectious diseases caused by viruses. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Measles:

Measles is a highly infectious viral illness. Measles is spread by small droplets from the nose, throat or mouth of an infected person (often before it is obvious they have measles). Measles often begins with a fever, runny nose, hacking cough and conjunctivitis (eye inflammation). The rash appears 3-5 days after the onset of symptoms and spreads rapidly all over the body. Measles is often a severe disease complicated by ear infection and pneumonia (lung infection). Encephalitis (swelling of the brain) can also occur and can sometimes result in permanent brain damage or death.

Unimmunised children in the following groups are at particular risk from severe measles infection:

- children with chronic conditions such as cystic fibrosis, congenital heart or kidney disease, failure to thrive, Down's Syndrome
- children from the age of 1 year upwards in child care centres, family day care and playgroups
- children living in institutions
- Aboriginal and Torres Strait Islander children.

Mumps:

Mumps is an infectious viral disease spread by infected droplets of saliva. Symptoms often begin with chilly sensations, headache, loss of appetite, general unwellness and fever. The salivary glands on one or both sides of the face can then become very painful and swollen.

Complications include meningoencephalitis (swelling around the brain) and in older patients the disease may involve other organs e.g. testes in males.

Rubella (German measles):

Rubella is generally a mild infectious viral illness spread by airborne droplets. It can cause mild fever, general unwellness, swollen glands and mild red rash. It often goes unnoticed in adolescents and adults. However rubella can cause miscarriage, stillbirth or birth defects in infants born to mothers infected with rubella during the early months of pregnancy.

Vaccination is the best way to protect against these severe diseases. The vaccine will not protect against diseases caused by other types of viruses or organisms.

2. What should I know before I am given PRIORIX?

Warnings

Do not receive PRIORIX if:

- you have/your child has had an allergic reaction to PRIORIX or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue
- you have/your child has ever had a severe allergic reaction to eggs or anything that contained eggs. Signs of an allergic reaction are listed above
- you have/your child has had PRIORIX or another MMR vaccine before and became unwell, tell your doctor or nurse before the next dose is given
- you have/your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated
- you have/your child has lowered immunity. This can occur in persons:
    - with inherited (or family history of) immune deficiency conditions
    - with abnormal blood conditions or blood protein (immunoglobulin) disorders
    - with cancer
    - receiving or who have received certain drugs (i.e. cyclosporin, high dose corticosteroids, and cancer medicines)
    - receiving or who have received radiation therapy
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

PRIORIX may generally be given to people with Human Immunodeficiency Virus (HIV) infection.

If needed, you can talk to your doctor about use of PRIORIX in HIV-positive people.

If you are not sure whether PRIORIX should be given, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you/your child.

Check with your doctor if:

- you/your child have tuberculosis (TB) - PRIORIX may affect the tuberculin skin test. Tuberculin testing may be done before or at the same time that PRIORIX is given
- you/your child has a history or family history of convulsions (fits or seizures)
- you/your child has a history or family history of allergic diseases
- you/you child has a skin allergy to neomycin
- you/your child have a bleeding disorder. Sometimes PRIORIX may need to be given differently in people with bleeding problems
- you/your child has a weakened immune system, or will be starting a medicine that weakens the immune system. You/your child should be closely monitored as the response to the vaccine may not be sufficient to ensure protection against the illness
- you have/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives
- you have/your child has received another vaccine within the last month
- you have/your child has received a blood or plasma transfusion, or been given gamma globulin or other immunoglobulin within the last 3 months. PRIORIX may be less effective if given within 3 months of these products. Your doctor will decide when to give the vaccine
- you are/your child is taking any prescription or OTC (over-the-counter) medicines. Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if PRIORIX is to be given with another vaccine or medicine
- you have/ your child has had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual
- you have/your child has fainted with a previous injection. Fainting can occur following, or even before, any needle injection.

During treatment, 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.

Pregnant women must not be vaccinated with PRIORIX.

You should not become pregnant for one month after receiving PRIORIX vaccination. During this time, you should use an effective method of birth control to avoid pregnancy.

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

Your doctor will discuss with you the risks of receiving PRIORIX during breastfeeding.

3. What if I am taking other medicines?

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

Tell your doctor or nurse if you or your child has received another vaccine recently.

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

A different injection site will be used for each vaccine.

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

4. How is PRIORIX given?

The doctor or nurse will give PRIORIX as an injection.

If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

How much is given

PRIORIX is generally given as a single 0.5 mL dose. The same dose is used for children and adults.

How it is given

PRIORIX is injected under the skin (subcutaneously) or into muscle, either in the upper arm or in the outer thigh. PRIORIX is generally injected into the upper leg muscle in infants under 12 months of age. In children over 12 months of age, older children and adults, the injection may be given in the upper arm muscle.

PRIORIX should never be given into a vein.

When it is given

The first dose of PRIORIX is generally given to children at 12 months of age. A second dose is then administered to children at 4-6 years of age; preferably before commencement at school.

If a dose is missed

If you/your child misses a scheduled dose, talk to your doctor or nurse and arrange another visit as soon as possible.

If you are given too much PRIORIX

If you think that you have been given too much PRIORIX you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given PRIORIX?

Things you should do

It is advised to remain in the clinic for about 15 minutes after receiving the injection. There is a risk of allergic reactions. These may be local or widespread rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness. These reactions will usually occur before leaving the doctor's surgery. If these symptoms occur, you should contact a doctor immediately.

Tell your doctor that you/your child has received PRIORIX if:

- you/your child are to have a tuberculin skin test for tuberculosis within 4-6 weeks after vaccination. The results of the test may be affected by the vaccine
- you/your child are to have another vaccine within 1 month after vaccination
- you/your child are to have a blood or plasma transfusion, or be given gamma globulin or other immunoglobulin within 2 weeks after vaccination.

Things you should not do

- Do not become pregnant for one month after receiving PRIORIX vaccination. Talk to your doctor as soon as possible, if you do become pregnant within this time.

Looking after your vaccine

PRIORIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store PRIORIX always:

- keep it in the refrigerator stored between 2°C and 8°C. DO NOT STORE PRIORIX IN THE FREEZER. Do not store it in the bathroom, near the sink, or leave it in the car on hot days. Avoid exposing the vaccine to sunlight
- keep it in the original pack until it is time for it to be given.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

Ask your pharmacist what to do with any left over PRIORIX that has expired or has not been used.

6. Are there any side effects?

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

The chance of your child having a serious side effect is very much less than the chance of you or your child having a permanent injury from the natural infections.

Most unwanted effects with PRIORIX are mild. These effects, as with other vaccines, generally occur around the injection site.

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
General disorders and administration site conditions: • pain, redness and swelling at the injection site • fever greater than or equal to 38°C (rectal) • fever greater than 39.5°C (rectal). **Infections and immune system disorders:** • upper respiratory tract infection • infection of the middle ear • viral infection • pneumonia • cold sores • shingles • mumps like symptoms (including transient, painful swelling of the testicles and swollen glands in the neck). **Gastrointestinal disorders:** • diarrhoea • vomiting • stomach pain or discomfort. **Metabolic disorders:** • loss of appetite. **Musculoskeletal disorders:** • joint and muscle pain. **Lymphatic disorders:** • swollen glands in the cheek, neck, armpit or groin.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
Less serious side effects	**What to do**
Psychiatric disorders: • nervousness • abnormal crying • not being able to sleep (insomnia). **Respiratory and mouth disorders:** • bronchitis • cough • runny nose	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

• sore throat and discomfort when swallowing • harsh breathing sounds • swelling of mouth and throat • toothache. **Eye disorders:** • discharge with itching of the eyes and crusty eyelids (conjunctivitis). **Skin disorders:** • rash (spots and/or blisters) • itchiness • temporary lumpy rash that may affect the skin, mouth and other parts of the body • bleeding or bruising more easily than normal which may be associated with skin rashes/peeling or fever.	

Serious side effects

Serious side effects	What to do
Nervous system disorders: • seizures with fever • infection or inflammation of the nervous system resulting in temporary loss of control of bodily movements, walking or sensation changes • feeling generally unwell, dizziness, tiredness • headache. **Infections and immune system disorders:** • allergic reaction • infection around the brain or spinal cord (meningitis).	**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.**

Tell your doctor or pharmacist if you notice anything else that may be making you 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 experience, you can report side effects to the Therapeutic Goods Administration online at 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.

7. Product details

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

What PRIORIX contains

Active ingredients (main ingredients)	Live weakened measles, mumps and rubella viruses in a dry powder. Each 0.5 mL dose contains not less than: • $10^{3.0}$ CCID50 (cell culture infectious dose 50%) of the Schwarz measles • $10^{3.7}$ CCID50 of the RIT 4385 mumps, and • $10^{3.0}$ CCID50 of the Wistar RA 27/3 rubella virus strains.
Other ingredients (inactive ingredients)	• lactose • amino acids • sorbitol • mannitol Neomycin sulphate is present as a residual from the manufacturing process. The vaccine is mixed with sterile Water for Injection before use. 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.
Potential allergens	• lactose • neomycin • eggs

Do not receive this vaccine if you are allergic to any of these ingredients.

What PRIORIX looks like

PRIORIX is presented as a powder and a water diluent for solution for injection. The powder and water diluent have to be mixed together before vaccination.

The powder is a whitish to slightly pink coloured cake, a portion of which may be yellowish to slightly orange, in a glass vial. This is mixed (reconstituted) with water diluent supplied in a prefilled syringe. The water diluent is clear and colourless.

The reconstituted vaccine may vary in colour from clear peach to fuchsia pink.

The vaccine should be injected as soon as possible after reconstitution, and no later than 8 hours after reconstitution.

PRIORIX (AUST R 97842) is available in pack sizes of 1 or 10 doses.

Not all pack sizes may be available.

Who distributes PRIORIX

GlaxoSmithKline Australia Pty Ltd

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www.gsk.com.au

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