PRIORIX-TETRA

Measles, mumps, rubella and varicella vaccine (live, attenuated)

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-TETRA?

PRIORIX-TETRA is a vaccine used to prevent four diseases: measles, mumps, rubella (German measles) and varicella (chickenpox).

Measles, mumps, rubella and varicella are all infectious diseases caused by viruses. 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-TETRA? in the full CMI.

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

Do not use if you have ever had an allergic reaction to PRIORIX-TETRA 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 am given PRIORIX-TETRA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRIORIX-TETRA 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-TETRA given?

The doctor or nurse will give PRIORIX-TETRA as an injection. PRIORIX-TETRA is generally injected into the upper leg in infants under 12 months of age. In children over 12 months of age the injection may be given in the upper arm.

PRIORIX-TETRA is generally given as a single 0.5 mL dose.

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

5. What should I know while being given PRIORIX-TETRA?

Things you should do	• Before receiving PRIORIX-TETRA tell your doctor if you have any medical problems such as a history or family history of convulsions (fits or seizures), a history or family history of allergic diseases, a skin allergy to neomycin, a bleeding disorder (sometimes PRIORIX-TETRA may need to be given differently in people with bleeding problems) or a weakened immune system. Your child should be closely monitored as the response to the vaccine may not be sufficient to ensure protection against the illness. • Remind any doctor or pharmacist you visit that you have been given PRIORIX-TETRA.
Things you should not do	• Do not recieve PRIORIX-TETRA if you or your child has an allergic reaction to any ingredient in the vaccine, to eggs or anything that contains eggs. The ingredients are listed at the end of this leaflet.
Looking after your vaccine	• PRIORIX-TETRA is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store PRIORIX-TETRA 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 while being given PRIORIX-TETRA? in the full CMI.

6. Are there any side effects?

The following very common or common side effects that are observed with PRIORIX-TETRA include pain, redness and swelling around the injection site, fever greater than 37.5°C, irritability, rash (spots and/or blisters).

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-TETRA

Active ingredients: Measles, mumps, rubella and varicella vaccine (live, attenuated)

Consumer Medicine Information (CMI)

This leaflet provides important information about PRIORIX-TETRA. **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-TETRA.**

Where to find information in this leaflet:

1. Why am I being given PRIORIX-TETRA?

PRIORIX-TETRA is a vaccine used to prevent four diseases: measles, mumps, rubella (German measles) and varicella (chickenpox).

Measles, mumps, rubella and varicella 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 childcare 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.

Varicella (Chickenpox)

Chickenpox is a highly infectious disease, which usually causes an itchy, red rash with blisters. After about 1 week, most of the blisters have normally crusted over. The rash can appear on the face, scalp, body, or in and around the mouth, eyes and bottom. Other symptoms can include fever, headaches, chills, and muscle and/or joint aches and pains. Sometimes disease complications can occur such as bacterial infection of the skin (often due to scratching of the itchy rash/crusts), inflammation of the brain (varicella encephalitis), and lung infection (varicella pneumonia).

Full recovery from chickenpox generally occurs; however, later in life the virus can become active again. This condition is known as shingles or Herpes zoster.

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.

Like other varicella vaccines, PRIORIX-TETRA cannot completely protect your child against catching chickenpox. However, people who have been vaccinated and catch chickenpox usually have a very mild disease, compared with people who have not been vaccinated.

Although PRIORIX-TETRA contains live viruses, they are too weak to cause severe disease in healthy people. Occasionally, some spots, blisters and fever may appear in the first two weeks after vaccination.

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

Warnings

Do not receive PRIORIX-TETRA if:

- your child has had an allergic reaction to PRIORIX-TETRA, 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

- your child is known to be allergic to neomycin. Signs of an allergic reaction are listed above. If your child has a history of skin allergy to neomycin they can still be vaccinated
- your child has had PRIORIX-TETRA or another vaccine containing measles, mumps, rubella or varicella before and became unwell, tell your doctor or nurse before the next dose is given
- 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
- your child has ever had a severe allergic reaction to eggs or anything that contained eggs
- you are or think you may be pregnant or if you intend to become pregnant within one month. Your doctor will discuss with you the risks of receiving PRIORIX-TETRA prior to or during pregnancy
- 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.

If you are not sure whether PRIORIX-TETRA 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/or your child.

Check with your doctor if:

- your child has any medical problems such as:
    - a history or family history of convulsions (fits or seizures)
    - a history or family history of allergic diseases
    - a skin allergy to neomycin
    - a bleeding disorder. Sometimes PRIORIX-TETRA may need to be given differently in people with bleeding problems
    - a weakened immune system, or will be starting a medicine that weakens the immune system. Your child should be closely monitored as the response to the vaccine may not be sufficient to ensure protection against the illness
- your child has allergies to any other medicines or substances, such as dyes, foods or preservatives
- your child has had any testing for tuberculosis (TB). PRIORIX-TETRA may affect the result of the tuberculin test
- your child has received another vaccine within the last month
- your child has received a blood or plasma transfusion, or been given gamma globulin or other immunoglobulin within the last 3 months. PRIORIX-TETRA may be less effective if given within 3 months of these products. Your doctor will decide when to give the vaccine.

Fainting can occur following, or even before, any needle injection, therefore, tell the doctor or nurse if you/your child has fainted with a previous 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-TETRA.

You should not become pregnant for one month after receiving PRIORIX-TETRA 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-TETRA 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.

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

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-TETRA.

4. How is PRIORIX-TETRA given?

The doctor or nurse will give PRIORIX-TETRA 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-TETRA is generally given as a single 0.5 mL dose.

How it is given

The vaccine comes as a powder which is mixed with sterile water before use. PRIORIX-TETRA is injected under the skin (subcutaneously) or into the muscle (intramuscularly). PRIORIX-TETRA is generally injected into the upper leg in infants under 12 months of age. In children over 12 months of age the injection may be given in the upper arm.

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

PRIORIX-TETRA should never be given into a vein or into the skin.

When it will be given

The appropriate time and number of doses that will be given will be determined by your doctor on the basis of appropriate official recommendations.

If a dose is missed

If 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-TETRA

If you think that you have been given too much PRIORIX-TETRA, 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-TETRA?

Things you should do

It is advised to remain in the clinic for about 15 minutes after receiving the injection. There is a rare 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 you/your child has received PRIORIX-TETRA 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.

Remind any doctor or pharmacist you visit that you have received PRIORIX-TETRA.

Things you should not do

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

Looking after your vaccine

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

- keep PRIORIX-TETRA in the refrigerator stored between 2°C and 8°C. DO NOT STORE PRIORIX-TETRA 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 PRIORIX-TETRA 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-TETRA 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-TETRA 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 37.5°C* • fever greater than 39.5°C • feeling generally unwell, dizziness, tiredness (fatigue) • irritability • lack of energy. *Higher rates of fever were observed after administration of the first dose of PRIORIX-TETRA when compared to measles-mumps-rubella and varicella vaccines administered separately at the same visit. **Infections and immune system disorders:** • upper respiratory tract infection • infection of the middle ear • viral infection • pneumonia • bronchitis • 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.**

Serious side effects

Less serious side effects	What to do
Psychiatric disorders: • nervousness • crying • not being able to sleep (insomnia). **Respiratory and mouth disorders:** • cough • runny nose • 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) • chickenpox like rash • 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.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

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

Active ingredients (main ingredients)	Live weakened measles, mumps, rubella and varicella 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 • $10^{4.4}$ CCID50 of the RIT 4385 mumps • $10^{3.0}$ CCID50 of the Wistar RA 27/3 rubella and • $10^{3.3}$ PFU (plaque forming units) of the OKA varicella-zoster virus strains.
Other ingredients (inactive ingredients)	• lactose • amino acids • sorbitol • mannitol. The vaccine is mixed with sterile Water for Injection before use. Neomycin sulphate is present as a residual from the manufacturing process 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 sulphate • eggs.

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

What PRIORIX-TETRA looks like

PRIORIX-TETRA is presented as a powder and a solvent for solution for injection. The powder and the solvent must be mixed together before vaccination.

The powder is a whitish to slightly pink coloured cake, a portion of which may be yellowish.

The solvent is clear and colourless.

The powder is contained in a glass vial for 1 dose and the solvent is contained in a pre-filled syringe (0.5 mL) in the following pack sizes:

- 1 vial and 1 syringe (AUST R 107286)
- 10 vials and 10 syringes (AUST R 107286).

Who distributes PRIORIX-TETRA

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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