NEW ZEALAND DATA SHEET

1. PRODUCT NAME

PRIORIX powder for injection with diluent.

Live trivalent attenuated measles, mumps and rubella vaccine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PRIORIX is a lyophilised mixed preparation of the attenuated Schwarz measles, RIT 4385 mumps (derived from Jeryl Lynn strain) and Wistar RA 27/3 rubella strains of viruses, separately obtained by propagation either in chick embryo tissue cultures (mumps and measles) or MRC_5 human diploid cells (rubella).

PRIORIX meets the World Health Organisation requirements for manufacture of biological substances and for measles, mumps and rubella vaccines and combined vaccines (live).

Each 0.5 mL dose of the reconstituted vaccine contains not less than $10^{3.0}$ $CCID_{50}$ of the Schwarz measles, not less than $10^{3.7}$ $CCID_{50}$ of the RIT 4385 mumps, and not less than $10^{3.0}$ $CCID_{50}$ of the Wistar RA 27/3 rubella virus strains.

For the full list of excipients, see section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Powder for injection in a glass vial.

Diluent solution for injection in a glass pre-filled syringe or ampoule.

PRIORIX powder is presented as a whitish to slightly pink coloured cake, a portion of which may be yellowish to slightly orange . The sterile diluent is clear and colourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PRIORIX is indicated for the active immunisation against measles, mumps and rubella from 12 months of age.

The use of PRIORIX should be in accordance with official recommendations.

4.2 Dose and method of administration

Dose

A single dose of the reconstituted vaccine is 0.5 mL.

Method of Administration

For information on instructions on preparation or reconstitution please refer to section 6.6 Special precautions for disposal and other handling.

PRIORIX is for subcutaneous injection**,** although it can also be given by intramuscular injection, in the deltoid region or in the anterolateral area of the thigh (see section 4.4 Special warnings and precautions for use).

PRIORIX must not be administered intravascularly.

The vaccine should be administered subcutaneously in subjects with bleeding disorders (e.g. thrombocytopenia or any coagulation disorder).

4.3 Contraindications

PRIORIX is contraindicated in subjects with known hypersensitivity to neomycin or to any other component of the vaccine (for egg allergy, see section 4.4 Special warnings and precautions for use). A history of contact dermatitis to neomycin is not a contraindication.

PRIORIX is contraindicated in subjects having shown signs of hypersensitivity after previous administration of measles, mumps and/or rubella vaccines.

PRIORIX is contraindicated in subjects with severe humoral or cellular (primary or acquired) immunodeficiency e.g. symptomatic HIV infection (see section 4.4 Special warnings and precautions for use).

PRIORIX is contraindicated in patients on current or recent immunosuppressive therapy (includes high doses of corticosteroids but not topical or low-dose parenteral corticosteroids) (see section 4.4 Special warnings and precautions for use).

PRIORIX is contraindicated in pregnant women. Pregnancy should be avoided for one month after vaccination (see section 4.6 Fertility, pregnancy and lactation).

4.4 Special warnings and precautions for use

As with other vaccines, the administration of PRIORIX should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, however, is not a contraindication for vaccination.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Limited protection against measles may be obtained by vaccination up to 72 hours after exposure to natural measles.

Infants below 12 months of age may not respond sufficiently to the measles component of the vaccine, due to the possible persistence of maternal measles antibodies. This should not preclude the use of the vaccine in younger infants (<12

months) since vaccination may be indicated in some situations such as high-risk areas. In these circumstances revaccination at or after 12 months of age should be considered.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

The measles and mumps components of the vaccine are produced in chick embryo cell culture and may therefore contain traces of egg protein. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g. generalised urticaria, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after vaccination, although these types of reactions have been shown to be very rare. Individuals who have experienced anaphylaxis after egg ingestion should be vaccinated with extreme caution, with adequate treatment for anaphylaxis on hand should such a reaction occur (see section 4.3 Contraindications).

PRIORIX should be given with caution to persons with a history or family history of allergic diseases or those with a history or family history of convulsions.

Transmission of measles and mumps virus from vaccinees to susceptible contacts has never been documented. Pharyngeal excretion of the rubella virus is known to occur about 7 to 28 days after vaccination with peak excretion around the 11th day. However there is no evidence of transmission of this excreted vaccine virus to susceptible contacts.

A limited number of subjects received PRIORIX intramuscularly. An adequate immune response was obtained for all three components.

PRIORIX must not be administered intravascularly.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

Cases of worsening of thrombocytopenia and recurrence of thrombocytopenia in subjects who suffered thrombocytopenia after the first dose have been reported following vaccination with live measles, mumps and rubella vaccines. In such cases, the risk-benefit of immunising with PRIORIX should be carefully evaluated.

There is limited data on the use of PRIORIX in immunocompromised subjects, therefore vaccination should be considered with caution and only when, in the opinion of the physician, the benefits outweigh the risks (e.g. asymptomatic HIV subjects).

Immunocompromised subjects who have no contraindication for this vaccination (see section 4.3 Contraindications) may not respond as well as immunocompetent subjects, therefore some of these subjects may acquire measles, mumps or rubella despite appropriate vaccine administration. Immunocompromised subjects should be monitored carefully for signs of measles, mumps and rubella.

Due to the potential risk of decreased vaccine response and/or disseminated diseases, consideration should be given to the time interval between PRIORIX vaccination and immunosuppressive therapy (see section 4.3 Contraindications).

4.5 Interaction with other medicines and other forms of interaction

If tuberculin testing has to be done it should be carried out before or simultaneously with vaccination since it has been reported that live measles (and possibly mumps) vaccine may cause a temporary depression of tuberculin skin sensitivity. This anergy may last for 4-6 weeks and tuberculin testing should not be performed within that period after vaccination to avoid false negative results.

Clinical studies have demonstrated that PRIORIX can be given simultaneously with any of the following monovalent or combination vaccines: hexavalent vaccine (DTPa-HBV-IPV/Hib), diphtheria-tetanus-acellular pertussis vaccine (DTPa), reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa), *Haemophilus influenzae* type b vaccine (Hib), inactivated polio vaccine (IPV), hepatitis B vaccine (HBV), hepatitis A vaccine (HAV), meningococcal serogroup B vaccine (MenB), meningococcal serogroup C conjugate vaccine (MenC), meningococcal serogroups A, C, W-135 and Y conjugate vaccine (MenACWY), varicella vaccine and pneumococcal conjugate vaccine (PCV).

In addition, it is generally accepted that combined measles, mumps and rubella vaccine may be given at the same time as the oral polio vaccine (OPV) or the diphtheria-tetanus-whole cell pertussis vaccine (DTPw).

If PRIORIX is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

If PRIORIX cannot be given at the same time as other live attenuated viral vaccines indicated in this age group, an interval of at least one month should be left between both vaccinations.

In subjects who have received human gammaglobulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired mumps, measles and rubella antibodies.

PRIORIX may be given as a booster dose in subjects who have previously been vaccinated with another measles mumps and rubella combined vaccine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Pregnant women must not be vaccinated with PRIORIX. Pregnancy should be avoided for one month after vaccination. Women who intend to become pregnant should be advised to delay pregnancy.

Studies have not been conducted with PRIORIX in pregnant women.

In a literature review of more than 3,500 susceptible women who were unknowingly in early stages of pregnancy when vaccinated with a rubella containing vaccine, no cases of congenital rubella syndrome were reported. Post-marketing surveillance identified congenital rubella syndrome associated with a rubella vaccine strain (Wistar RA 27/3) following inadvertent vaccination of a pregnant woman with measles, mumps and rubella vaccine.

Foetal damage has not been documented when measles or mumps vaccines have been given to pregnant women.

Breastfeeding

There is no human data regarding use in breastfeeding women. Persons can be vaccinated where the benefit outweighs the risk.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Summary of the safety profile

The safety profile presented below is based on a total of approximately 12,000 subjects administered PRIORIX in clinical trials.

In controlled clinical studies, signs and symptoms were actively monitored during a 42-day follow-up period. The vaccinees were also requested to report any clinical events during the study period.

List of adverse reactions

Frequencies are reported as:
Very common: ≥ 10%
Common: ≥ 1% and < 10%
Uncommon: ≥ 0.1% and < 1%
Rare: ≥ 0.01% and < 0.1%
Very rare: < 0.01%

Adverse reactions from clinical trials

System organ class	Frequency	Adverse reactions
Infections and infestations	Common	upper respiratory tract infection
	Uncommon	otitis media
Blood and lymphatic system disorders	Uncommon	lymphadenopathy
Immune system disorders	Rare	allergic reactions
Metabolism and nutrition disorders	Uncommon	anorexia
Psychiatric disorders	Uncommon	nervousness, abnormal crying, insomnia
Nervous system disorders	Rare	febrile convulsions
Eye disorders	Uncommon	conjunctivitis
Respiratory, thoracic and mediastinal disorders	Uncommon	bronchitis, cough

Gastrointestinal disorders	Uncommon	parotid gland enlargement, diarrhoea, vomiting
Skin and subcutaneous tissue disorders	Common	rash
General disorders and administration site conditions	Very common	redness at the injection site, fever ≥38°C (rectal) or ≥37.5°C (axillary/oral)
	Common	pain and swelling at the injection site, fever >39.5°C (rectal) or >39°C (axillary/oral)

In general, the frequency category for adverse reactions was similar for the first and second vaccine doses. The exception to this was pain at the injection site which was "Common" after the first vaccine dose and "Very common" after the second vaccine dose.

Adverse reactions from spontaneous reporting

During post-marketing surveillance, the following reactions have been reported additionally in temporal association following PRIORIX vaccination:

System organ class	**Frequency**	**Adverse reactions**
Infections and infestations	Rare	meningitis, measles-like syndrome, mumps-like syndrome (including orchitis, epididymitis and parotitis)
Blood and lymphatic system disorders	Rare	thrombocytopenia, thrombocytopenic purpura
Immune system disorders	Rare	anaphylactic reactions
Nervous system disorders	Rare	encephalitis, cerebellitis, cerebellitis like symptoms (including transient gait disturbance and transient ataxia), Guillain Barré syndrome, transverse myelitis, peripheral neuritis
Vascular disorders	Rare	vasculitis (including Henoch Schonlein purpura and Kawasaki syndrome)
Skin and subcutaneous tissue disorders	Rare	erythema multiforme
Musculoskeletal and connective tissue disorders	Rare	arthralgia, arthritis

Accidental intravascular administration may give rise to severe reactions or even shock. Immediate measures depend on the severity of the reaction (see section 4.4 Special warnings and precautions for use).

In the comparative studies, a statistically significant lower incidence of local pain, redness and swelling was reported with PRIORIX compared with the comparator. The incidence of other adverse reactions listed above were similar in both vaccines.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via: https://pophealth.my.site.com/carmreportnz/s/}.

4.9 Overdose

Cases of overdose (up to 2 times the recommended dose) have been reported during post-marketing surveillance. No adverse events have been associated to the overdose.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Viral vaccine, ATC code: J07BD52

In clinical studies PRIORIX has been demonstrated to be highly immunogenic. Antibodies against measles were detected in 98.0%, against mumps in 96.1% and against rubella in 99.3% of previously seronegative vaccinees.

In comparative studies, antibodies against measles, mumps and rubella were detected in 98.7%, 95.5% and 99.5% of previously seronegative vaccinees who received PRIORIX compared to 96.9%, 96.9% and 99.5% in the group receiving a commercially available measles mumps and rubella combined vaccine.

Subjects followed up to 12 months following vaccination all remained seropositive for anti-measles and anti-rubella antibodies. 88.4% were still seropositive at month 12 for anti-mumps antibody. This percentage is in line with what was observed for the commercially available measles, mumps and rubella combined vaccine (87%).

Booster Immunisation

A booster dose of PRIORIX was administered to children aged 4 - 6 years or 11-12 years, who had been primed with a different MMR vaccine. All subjects aged 4-6 years who were seronegative at the time of booster, subsequently seroconverted. In subjects aged 11 -12 years who were seronegative at the time of booster, seroconversion rates of 85.7%, 93.5% and 100% were observed for measles, mumps and rubella respectively.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on general safety studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder: Lactose, amino acids, mannitol and sorbitol.

Diluent: Water for injections.

Residues: Neomycin sulphate

6.2 Incompatibilities

PRIORIX should not be mixed with other vaccines in the same syringe.

6.3 Shelf life

2 years.

After reconstitution, the vaccine should be injected as soon as possible and not later than 8 hours after reconstitution.

6.4 Special precautions for storage

PRIORIX should be stored in a refrigerator between 2°C and 8°C.

Do not freeze.

During transport, recommended conditions of storage should be respected, particularly in hot climates.

For storage conditions after reconstitution of the medicine, see section 6.3 Shelf life.

6.5 Nature and contents of container

PRIORIX vaccine: monodose glass vials in packs of 1 or 10.

Diluent: glass ampoules or prefilled syringes, 0.5 mL in packs of 1 or 10.

Vials/prefilled syringes are made of neutral glass type I, which conforms to European Pharmacopoeia Requirements.

6.6 Special precautions for disposal and other handling

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

The diluent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to reconstitution or administration. In the event of either being observed, do not use the diluent or the reconstituted vaccine.

Inject the entire contents of the syringe, using a new needle for administration.

<u>Instructions for reconstitution of the vaccine with diluent presented in ampoules</u>

PRIORIX must be reconstituted by adding the entire contents of the supplied ampoule of diluent to the vial containing the powder. The mixture should be well shaken until the powder is completely dissolved in the diluent.

After reconstitution, the vaccine should be used promptly.

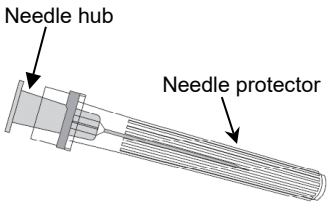
Withdraw the entire contents of the vial. Inject the entire contents of the syringe, using a new needle for administration.

<u>Instructions for reconstitution of the vaccine with the diluent presented in pre-filled syringe</u>

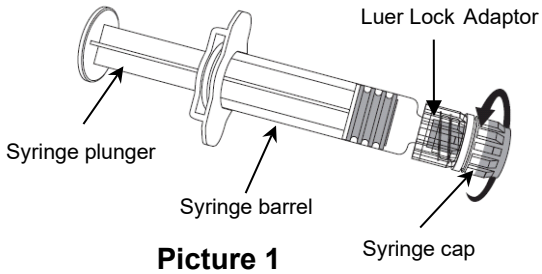
PRIORIX must be reconstituted by adding the entire contents of the pre-filled syringe of diluent to the vial containing the powder.

To attach a needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with PRIORIX might be slightly different than the syringe illustrated.

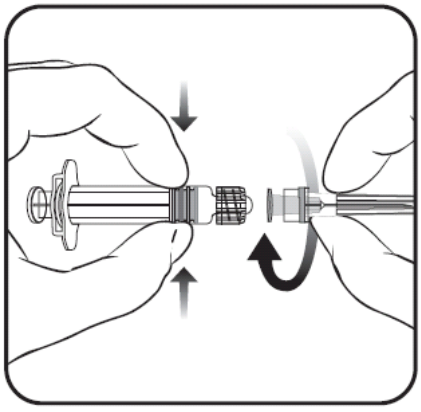
Needle



Syringe



Picture 1



Picture 2

Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock Adaptor (LLA), and maintain the needle in the axis of the syringe (as illustrated in picture 2). Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1).

2. Attach a needle to the syringe by gently connecting the needle hub into the LLA and rotate a quarter turn clockwise until you feel it lock (as illustrated in picture 2).

3. Remove the needle protector, which may be stiff.

4. Add the diluent to the powder. The mixture should be well shaken until the powder is completely dissolved in the diluent.

After reconstitution, the vaccine should be used promptly.

5. Withdraw the entire contents of the vial.

6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach an injection needle by repeating step 2 above.

Inject the entire contents of the syringe.Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
New Zealand

Phone: (09) 367 2900
Facsimile: (09) 367 2910

9. DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine: 26 August 1999

10. DATE OF REVISION OF THE TEXT

03 October 2025

Summary table of changes:

Section changed	Summary of new information
3.0	Revised description and composition of the product.