

## PRODUCT MONOGRAPH

### **PRIORIX<sup>®</sup>**

Combined measles, mumps and rubella vaccine, live, attenuated

Lyophilized powder for injection

Meets WHO requirements

Active immunizing agent against infection by measles, mumps and rubella

GlaxoSmithKline Inc.  
7333 Mississauga Road  
Mississauga, Ontario  
L5N 6L4

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## PRIORIX®

combined measles, mumps and rubella vaccine, live, attenuated

### PART I: HEALTH PROFESSIONAL INFORMATION

#### SUMMARY PRODUCT INFORMATION

<b>Route of Administration</b>	<b>Dosage Form / Strength</b>	<b>Clinically Relevant Nonmedicinal Ingredients</b>
Subcutaneous or Intramuscular injection	Lyophilized powder for injection / Not less than: $10_{3.0}$ CCID <sub>50</sub> of the Schwarz measles; $10_{3.7}$ CCID <sub>50</sub> of the RIT 4385 mumps; and $10_{3.0}$ CCID <sub>50</sub> of the Wistar RA 27/3 rubella virus strains/ per 0.5 mL dose.	amino acids, human albumin, lactose, mannitol, neomycin sulphate and sorbitol.

#### DESCRIPTION

PRIORIX® is a lyophilized 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 MRC5 human diploid cells (rubella).

#### INDICATIONS AND CLINICAL USE

PRIORIX® (combined measles, mumps and rubella vaccine, live, attenuated) is indicated for:

- active immunization against infection by measles, mumps and rubella.

#### **Pediatrics:**

A single dose is recommended routinely for children on, or as soon as practicable after, their first birthday. Older children who have no documented evidence of having received the vaccine should also be vaccinated.

## CONTRAINDICATIONS

PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated):

- as with other vaccines, administration of PRIORIX<sup>®</sup> should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, however, is not a contraindication for vaccination.
- is contraindicated in subjects with known systemic hypersensitivity to neomycin or to any other component of the vaccine (see also WARNINGS AND PRECAUTIONS). A history of contact dermatitis to neomycin is not a contraindication.
- should not be given to subjects with impaired immune responses. These include patients with primary or secondary immunodeficiencies. However, measles, mumps, and rubella combined vaccines can be given to asymptomatic HIV-infected persons without adverse consequences to their illness and may be considered for those who are symptomatic.
- is contraindicated in pregnant women. Women of child-bearing potential should be advised to avoid pregnancy for three months following vaccination (see also WARNINGS AND PRECAUTIONS).

When other susceptible persons with immune deficiencies are exposed to measles, passive immunization with immune globulin [human (IG)] should be given as soon as possible. It is desirable to immunize close contacts of immunocompromised individuals in order to minimize the risk of exposure of the latter to measles.

## WARNINGS AND PRECAUTIONS

### **General**

PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) **should under no circumstances be administered intravenously.**

A limited number of subjects received PRIORIX<sup>®</sup> intramuscularly. An adequate immune response was obtained for all three components.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they may 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.

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

Vaccines produced in chick embryo tissue cultures have been shown not to contain egg proteins in sufficient amounts to elicit hypersensitivity reactions. Persons having egg allergies, that are not anaphylactic in nature, may be considered for vaccination. Anaphylactic reactions include: urticaria, swelling of the mouth and throat, difficulty in breathing or hypotension.

PRIORIX<sup>®</sup> 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 not been documented. Pharyngeal excretion of the rubella virus is known to occur approximately 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.

### **Hematologic**

Individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination with measles-mumps-rubella vaccines. In addition, individuals who experienced thrombocytopenia with the first dose of vaccine may develop thrombocytopenia with repeat doses. Serologic status may be evaluated to determine whether or not additional doses of vaccine are needed. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases (see ADVERSE REACTIONS).

### **Special Populations**

**Pregnant Women:** PRIORIX<sup>®</sup> is contraindicated in pregnant women. Women of child-bearing potential should be advised to avoid pregnancy for three months following vaccination.

**Nursing Women:** There is no human data regarding use in breastfeeding women. Nursing mothers may be vaccinated where, in the judgement of the health professional, the benefit outweighs the risk.

**Pediatrics:** 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.

Febrile seizures occasionally follow vaccination, particularly in children who have previously had convulsions or whose sibling or parents have a history of convulsions. However, the risk is low and the benefit of immunizing children greatly outweighs any potential risk associated with febrile seizures.

No special precautions are necessary for children with minor egg hypersensitivity who are able to ingest small quantities of egg uneventfully. No special measures are necessary in children who have never been fed eggs before MMR immunization. Prior egg ingestion should not be a prerequisite for MMR immunization.

Under certain conditions, vaccine may be recommended for children < 1 year of age. When an infant < 12 months of age is at high risk of exposure for measles or is travelling abroad to an area where measles is common, measles vaccine alone or as MMR may be given as early as 6 months of age.

Under these circumstances, or if vaccine was inappropriately given before the child's first birthday, such children should receive two additional doses of MMR after the first birthday.

Susceptible persons > 12 months of age who are exposed to measles may be protected from disease if measles vaccine is given within 72 hours after exposure. There are no known adverse effects of vaccine given to persons incubating measles. However, immune globulin (IG) given within 6 days after exposure can modify or prevent disease and may be used for this purpose in infants < 12 months of age, persons for whom vaccine is contraindicated or those for whom more than 72 hours but less than 1 week have elapsed since exposure. Unless contraindicated, individuals who receive IG should receive measles vaccine later, at the intervals specified in the Canadian Immunization Guide.

PRIORIX<sup>®</sup> is indicated for most infants infected with the human deficiency virus (HIV) whose immune function at 12 to 15 months of age is compatible with safe MMR vaccination. Consultation with an expert is required in the case of HIV-infected children to determine the presence or absence of significant immunodeficiency in individual cases. Measles revaccination may still be appropriate for HIV-infected persons with moderate immunodeficiency if there is a high risk of measles in the local community or travel to an area where measles is endemic. Consultation with local public health authorities will help determine the local level of measles activity and risk to travellers abroad. Because the response to prior immunization may be impaired, HIV-infected children should receive IG after recognized exposure to measles.

### **Monitoring and Laboratory Tests**

If tuberculin testing is required, 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 in order to avoid false negative results.

## ADVERSE REACTIONS

### **Clinical Trial Adverse Drug Reactions**

*Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.*

In controlled clinical studies, signs and symptoms were actively monitored on more than 5400 vaccinees during a 42-day follow-up period. The vaccinees were also requested to report any clinical events during the study period. The following adverse reactions were reported by the vaccinees in order of frequency:

Local Redness	7.2%
Rash	7.1%
Fever	6.4%
Local Pain	3.1%
Local Swelling	2.6%
Parotid Swelling	0.7%
Febrile Convulsions	0.1%

During the active monitoring of signs and symptoms, in total, less than 6% of vaccinees exhibited one of the following events considered as possibly related to vaccination with PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated): nervousness (0.90%), pharyngitis (0.68%), upper respiratory tract infection (0.57%), rhinitis (0.56%), diarrhea (0.54%), bronchitis (0.52%), vomiting (0.43%), coughing (0.39%), viral infection (0.31%) and otitis media (0.30%).

Very rare allergic reactions, including anaphylactoid reactions and thrombocytopenic purpura have been reported.

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

### **Post-Market Adverse Drug Reactions**

During post-marketing surveillance, thrombocytopenia and thrombocytopenic purpura have been reported very rarely in temporal association with PRIORIX<sup>®</sup> vaccination.

Cases of aseptic meningitis have been reported very rarely following vaccination with PRIORIX<sup>®</sup>. In one case, Jeryl-Lynn strain mumps virus was identified in cerebrospinal fluid using the polymerase chain reaction. This case resolved without sequelae.

## **DRUG INTERACTIONS**

### **Overview**

Although data on the concomitant administration of PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) and other vaccines are not yet available, it is generally accepted that measles, mumps and rubella combined vaccine may be given at the same time as the oral polio vaccine (OPV) or inactivated polio vaccine (IPV), the injectable trivalent diphtheria, tetanus and pertussis vaccines (DTPw/DTPa) and *Haemophilus influenzae* type b (Hib) if they are administered at separate injection sites.

If it is not possible to administer PRIORIX<sup>®</sup> at the same time as other live attenuated vaccines, it is recommended that an interval of at least one month should be left between vaccinations.

Administration of PRIORIX<sup>®</sup> to subjects who have received human gammaglobulins or a blood transfusion should be delayed for a minimum of three months as there is a possibility of vaccine failure due to passively acquired mumps, measles and rubella antibodies.

According to the Canadian Immunization Guide, if administration of an IG preparation becomes necessary after MMR vaccine or its individual component vaccines have been given, interference can also occur. If the interval between administration of any of these vaccines and subsequent administration of an IG preparation is < 14 days, immunization should be repeated at 3 months or longer, unless serologic test results indicate that antibodies were produced. If the IG product is given more than 14 days after the vaccine, immunization does not have to be repeated.

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

PRIORIX<sup>®</sup> should not be mixed with other vaccines in the same syringe.

## **DOSAGE AND ADMINISTRATION**

### **Recommended Dose and Dosage Adjustment**

The Canadian Immunization Guide recommends immunization at 12 months of age, or as soon as practicable thereafter. A second dose of MMR is recommended, at least 1 month after the first dose for the purpose of better measles protection. For convenience, options include giving it with the next scheduled vaccination at 18 months of age or with school entry (4-6 years) vaccinations (depending on the provincial/territorial policy), or at any intervening age that is practicable. The need for a second dose of mumps and rubella vaccine is not established but may benefit (given for convenience as MMR).

A single 0.5 mL dose of the reconstituted vaccine is recommended.

### **Administration**

It is recommended that PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) be given by subcutaneous injection, although it may also be given by intramuscular injection. PRIORIX<sup>®</sup> should under no circumstances be administered intravenously.

### **Directions for Reconstitution**

The diluent (sterile water for injection) and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine as appropriate.

#### ***Withdrawing the sterile diluent from the ampoule:***

Disinfect the neck of the ampoule of sterile diluent and allow to dry. Using a sterile towel, break off the top of the ampoule at the scored line. Using a sterile syringe and needle, withdraw the diluent from the ampoule, ensuring that the point remains immersed throughout the withdrawal.

#### ***Cartons containing a syringe of diluent:***

Syringe is ready for use in reconstituting the lyophilized vaccine.

#### ***Reconstitution of the lyophilized vaccine:***

The vaccine should be reconstituted by adding the entire contents of the supplied container of diluent to the vial containing the pellet. Disinfect the rubber stopper of the vial of vaccine and allow to dry. Holding the plunger of the syringe containing the diluent, pierce the center of the rubber stopper of the vial and inject the sterile diluent into the vial containing the lyophilized vaccine. Shake the vial gently until the pellet is completely dissolved in the diluent.

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

Reconstituted vaccine should be injected as soon as possible, within 8 hours of reconstitution.

### **OVERDOSAGE**

No information is available.

## **ACTION AND CLINICAL PHARMACOLOGY**

See Part II SCIENTIFIC INFORMATION: CLINICAL TRIALS Section.

### **Duration of Effect**

All subjects followed up to 12 months after vaccination remained seropositive for anti-measles and anti-rubella antibodies. At month 12, 88.4% were still seropositive for anti-mumps antibody. This percentage is comparable to that observed for the commercially available measles, mumps and rubella combined vaccine (87%).

## **STORAGE AND STABILITY**

The vaccine should not be used beyond the expiry date stamped on the vial label and outer packaging. The diluent should not be used beyond the expiry date stamped on the syringe or ampoule label and outer packaging.

PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) should be stored in a refrigerator at 2 to 8°C. Care should be taken to ensure appropriate storage conditions during transport.

Reconstituted vaccine should not be kept for more than 8 hours.

To conserve refrigerator space, the diluent may be stored separately at room temperature.

## **DOSAGE FORMS, COMPOSITION AND PACKAGING**

### **Dosage Forms and Packaging**

PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) is available in packages of 10 vials in the following combinations of lyophilized vaccine and diluent:

- Boxes of monodose vials of vaccine with 10 ampoules of diluent.

### **Composition**

PRIORIX<sup>®</sup> is a lyophilized 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 MRC5 human diploid cells (rubella).

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

The vaccine also contains amino acids, human albumin, lactose, mannitol, neomycin sulphate and sorbitol as excipients.

PRIORIX<sup>®</sup> meets the World Health Organization requirements for manufacture of biological substances and for measles, mumps and rubella vaccines and combined vaccines (live).

## **PART II: SCIENTIFIC INFORMATION**

### **PHARMACEUTICAL INFORMATION**

#### **Drug Substance**

Proper name: combined measles, mumps and rubella vaccine, live, attenuated

#### **Product Characteristics**

PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) is a whitish to slightly pink coloured cake or powder contained in a glass vial sealed with a rubber stopper. The diluent (sterile water for injection) is clear and colourless. Due to minor variation of its pH, the colour of the reconstituted vaccine may vary from clear peach to fuchsia-pink coloured solution without deterioration of the vaccine potency.

### **CLINICAL TRIALS**

#### **Pharmacodynamics**

In clinical studies PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) 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% respectively of previously seronegative vaccinees who received PRIORIX<sup>®</sup> compared to 96.9%, 96.9% and 99.5% respectively in the group receiving a commercially available measles mumps and rubella combined vaccine.

### **DETAILED PHARMACOLOGY**

Not applicable.

### **MICROBIOLOGY**

Not applicable.

### **TOXICOLOGY**

Not applicable.

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**PART III: CONSUMER INFORMATION****PRIORIX<sup>®</sup>**

combined measles, mumps and rubella vaccine, live, attenuated

This leaflet is part III of a three-part "Product Monograph" published for PRIORIX<sup>®</sup> (combined measles, mumps and rubella vaccine, live, attenuated) approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRIORIX<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

PRIORIX<sup>®</sup> is a vaccine used for protection against measles, mumps and rubella.

**What it does:**

PRIORIX<sup>®</sup> protects your child against measles, mumps and rubella. It works by helping the body to make its own antibodies which protect your child against these diseases.

**When it should not be used:**

PRIORIX<sup>®</sup>

- vaccination should be delayed if your child has an infection with a high temperature.
- vaccination should not be received if you think your child has previously had an allergic reaction to neomycin (an antibiotic contained in the vaccine) or any other component of the vaccine.  
Signs of an allergic reaction may include skin rash, shortness of breath and swelling of the face and tongue.
- vaccination should not be received if your child's defences against infections (immunity mechanisms) are impaired.
- should not be administered to pregnant women. Furthermore, pregnancy should be avoided for three months after vaccination. Breast-feeding women can be vaccinated only where there is a clear need for vaccination.

**What the medicinal ingredient is:**

Each 0.5 mL dose of the reconstituted vaccine contains as active ingredients not less than  $10_{3.0}$  CCID<sub>50</sub> of the Schwarz measles, not less than  $10_{3.7}$  CCID<sub>50</sub> of the RIT 4385 mumps, and not less than  $10_{3.0}$  CCID<sub>50</sub> of the Wistar RA 27/3 rubella virus strains.

**What the important nonmedicinal ingredients are:**

PRIORIX<sup>®</sup> contains as inactive ingredients: amino acids, human albumin, lactose, mannitol, neomycin sulphate and sorbitol.

**What dosage forms it comes in:**

PRIORIX<sup>®</sup> is provided as a freeze-dried vaccine for reconstitution with sterile diluent (water for injection).

**WARNINGS AND PRECAUTIONS**

BEFORE you use PRIORIX<sup>®</sup> talk to your doctor or pharmacist if:

- your child has a high temperature (over 38°C), previous allergic reactions, impaired defence against infections, is pregnant, or breast-feeding.
- your child or somebody else in the family had convulsions or allergies.
- your child is taking any other medicine or has recently received any other vaccine.
- your child has any serious health problems.
- your child has a condition called thrombocytopenia (decreased platelets which may lead to unusual bleeding or bruising).

As with other vaccines, appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic events (severe allergic reaction that can be life threatening) following the administration of the vaccine.

**PROPER USE OF THIS MEDICATION**

The vaccine must be administered by a health professional.

A single 0.5 mL dose of the reconstituted vaccine is recommended.

**Usual dose:**

PRIORIX<sup>®</sup> will be injected under the skin or into a muscle.

PRIORIX<sup>®</sup> should not be administered intravenously (into a vein).

Different injectable vaccines should always be administered at different injection sites.

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

**Missed Dose:**

Make sure your child finishes the complete vaccination course. If not, your child may not be fully protected against infection.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all vaccines, PRIORIX® may occasionally cause unwanted effects.

As with other vaccines your child may feel pain at the injection site, or you may see some redness and swelling at this site. However, these reactions usually clear up within a few days.

Other reactions which can occur are fever, rash, swelling of the glands of the neck, convulsions.

Nervousness, coughing, respiratory tract infection, diarrhea (several loose bowel movements a day), vomiting, viral infection, earache, thrombocytopenia (decreased platelets which may lead to unusual bleeding or bruising) and meningitis (inflammation of the lining of the brain) have also been described after vaccination. If your child develops thrombocytopenia after 1 dose of the vaccine your doctor may do a blood test to see if your child has developed antibodies against measles, mumps and rubella.

If these symptoms continue or become severe, tell the doctor or nurse.

As with all injectable vaccines, there is an extremely small risk of a severe allergic reaction. (This can be recognised by symptoms such as itchy rash of the hands and feet, swelling of the eyes and face and difficulty in breathing or swallowing). Such reactions will usually occur before leaving the doctor's office, but in any event you should seek immediate treatment.

If the child develops any other symptom within days following the vaccination, tell the doctor as soon as possible.

*This is not a complete list of side effects. For any unexpected effects while taking PRIORIX®, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store your vaccine in a refrigerator at 2 to 8°C.

Store all vaccines out of the reach and sight of children.

The expiry date is shown on the label and packaging. The vaccine should not be used after this date.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

**For Vaccines:**

toll-free telephone: 1-800-363-6456  
 local telephone: 613-957-1340  
 fax: 613-998-6413

**By regular mail:**

Health Canada  
 Division of Immunization  
 L.C.D.C., Tunney's Pasture 0603E1  
 Ottawa, ON K1A 0L2

**For Drugs:**

toll-free telephone: 866-234-2345  
 toll-free fax 866-678-6789  
 By email: [cadrmp@hc-sc.gc.ca](mailto:cadrmp@hc-sc.gc.ca)

**By regular mail:**

National AR Centre  
 Marketed Health Products Safety and Effectiveness  
 Information Division  
 Marketed Health Products Directorate  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

**NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.**

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca>  
 or by contacting the sponsor, GlaxoSmithKline Inc.  
 7333 Mississauga Road  
 Mississauga, Ontario  
 L5N 6L4  
 1-800-387-7374

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