

**Drug of the Month**  
**Priorix® MMR Vaccine**

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use PRIORIX safely and effectively. See full prescribing information for PRIORIX.

**PRIORIX (Measles, Mumps, and Rubella Vaccine, Live), suspension for subcutaneous injection**

-----INDICATIONS AND USAGE-----

PRIORIX is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. (1)

-----DOSAGE AND ADMINISTRATION -----

For subcutaneous injection only.

Each dose is approximately 0.5 mL.

- The first dose is administered at 12 through 15 months of age. (2.1)
- The second dose is administered at 4 through 6 years of age. (2.1)

-----DOSAGE FORMS AND STRENGTHS -----

PRIORIX is a suspension for injection supplied as a single-dose vial of lyophilized antigen component to be reconstituted with the accompanying prefilled syringe of sterile water diluent component. A single dose after reconstitution is approximately 0.5 mL. (3)

-----CONTRAINDICATIONS-----

- Severe allergic reaction (e.g., anaphylaxis) to any component of PRIORIX, or after a previous dose of any measles, mumps, and rubella virus-containing vaccine. (4.1)
- Severe immunodeficiency. (4.2)

- **Pregnancy. (4.3, 8.1)**

----- **WARNINGS AND PRECAUTIONS** -----

- **There is a risk of febrile seizure following administration of PRIORIX. (5.2)**
- **Thrombocytopenia and thrombocytopenic purpura have been reported following vaccination with PRIORIX. (5.3)**
- **Syncope (fainting) can occur in association with administration of injectable vaccines, including PRIORIX. Procedures should be in place to avoid injury from fainting. (5.4)**
- **The tip caps of the prefilled syringes contain natural rubber latex, which may cause allergic reactions. (5.5)**

----- **ADVERSE REACTIONS** -----

**Most common solicited adverse reactions in clinical trials participants:**

- **12 through 15 months of age: local reactions were pain (26%) and redness (25%); systemic reactions were irritability (63%), loss of appetite (45%), drowsiness (45%), and fever(35%). (6.1)**
- **4 through 6 years of age: local reactions were pain (41%), redness (22%), and swelling (11%); systemic reactions were loss of appetite (21%), drowsiness (27%), and fever(24%). (6.1)**
- **7 years of age and older: local reactions were pain (12%) and redness (12%). (6.1)**

**To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or [www.vaers.hhs.gov](http://www.vaers.hhs.gov).**

----- **DRUG INTERACTIONS** -----

- **Administration of immune globulins and other blood products concurrently with PRIORIX may interfere with the expected immune**

response to the vaccine. (7.1)

- PRIORIX may result in a temporary suppression of tuberculin reactivity. (7.2)

-----USE IN SPECIFIC POPULATIONS -----

- Do not use during pregnancy. (8.1)
- Avoid pregnancy for 1 month following vaccination with PRIORIX. (8.1)

## 6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during postmarketing use of PRIORIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination with PRIORIX.

### Blood and Lymphatic System Disorders

Thrombocytopenia, thrombocytopenic purpura.

### Vascular Disorders

Vasculitis (including Henoch-Schönlein purpura and Kawasaki syndrome).

### Immune system Disorders

Anaphylactic reactions.

### Infections and Infestations

Meningitis, measles-like illness, mumps-like illness(including orchitis, epididymitis, and parotitis).

### Musculoskeletal and Connective Tissue Disorders

Arthralgia, arthritis.

### Nervous System Disorders

**Encephalitis, cerebellitis, cerebellitis-like symptoms (including transient gait disturbance and transient ataxia), Guillain-Barré syndrome, transverse myelitis, peripheral neuritis, afebrile seizures, syncope.**

#### **Skin and Subcutaneous Tissue Disorders**

**Erythema multiforme**

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 6/2022**