

Patient Information Leaflet

SCHEDULING STATUS:

S2

PRIORIX

Powder and diluent for solution for injection.

Contains sugar (mannitol 8mg/dose, anhydrous lactose 32 mg/dose, sorbitol 9 mg/dose)

Read all of this leaflet carefully before you or your child are vaccinated with PRIORIX.

PRIORIX is not for self-medication and must be administered by a healthcare professional.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist, nurse or other healthcare provider.
- PRIORIX has been prescribed for you personally or your child only and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What PRIORIX is and what it is used for
2. What you need to know before you receive PRIORIX
3. How to take PRIORIX
4. Possible side effects
5. How to store PRIORIX
6. Contents of the pack and other information.

1. WHAT PRIORIX IS AND WHAT IT IS USED FOR:

PRIORIX is a vaccine for use from 12 months of age to prevent infections caused by measles, mumps and rubella viruses. It provides protective immunity by encouraging the formation of antibodies against these diseases.

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE PRIORIX:

PRIORIX should not be administered to you or your child:

- if you/your child previously had an allergic reaction to PRIORIX, neomycin (an antibiotic) or to any ingredient contained in this vaccine. The active substances and other ingredients are listed at the beginning of this leaflet. However, if you have had a skin rash (dermatitis) after treatment with neomycin, you can still be vaccinated with PRIORIX
- if you/your child have previously had an allergic reaction to any vaccine against measles, mumps and rubella
- if you/your child have active untreated tuberculosis
- if you/your child have abnormal tumours or growths
- if you/your child have any severe illness, or take any medicine that weakens the immune system
- if you/your child have recently had a blood or plasma transfusion, or been given human immunoglobulin, your doctor may delay vaccination with PRIORIX for at least 3 months.

PRIORIX must not be given during pregnancy. Pregnancy should be avoided for one month following vaccination.

➔ Check with your doctor, if you think any of the above apply to you.

Warnings and precautions:

Tell your doctor or health care provider before being given the injection:

Take special care with PRIORIX:

Your doctor needs to know before you are given PRIORIX, if you or your child:

- have a severe infection with a high temperature (over 38 °C). A minor infection such as a cold should not be a problem, but talk to your doctor first
- have a history or family history of convulsions (fits)
- have a history or family history of allergies
- have ever had a severe allergic reaction to eggs or to anything containing eggs
- have had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual
- have a weakened immune system. You should be closely monitored as the responses to the vaccines may not be sufficient to ensure protection against the illness
- if your child is below the age of 12 months. Children in their first year of life may not develop a sufficient immune response (body's natural defence reaction) to the measles virus. Your doctor will advise you if additional doses of a measles containing vaccine are needed.

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

Other medicines and PRIORIX:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

If a tuberculin test (skin test to check for tuberculosis) is to be performed, it should be done either before, at the same time as, or 4 to 6 weeks after vaccination with PRIORIX, otherwise the result of the test may not be correct.

If you or your child has recently had a blood transfusion, or been given human immunoglobulin, your doctor may delay vaccination with PRIORIX for at least 3 months.

PRIORIX can be given at the same time as other childhood vaccines. A different place for the injection will be used for each vaccine.

Pregnancy, breastfeeding, and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you are given PRIORIX.

PRIORIX must not be given during pregnancy. It is important that you do not fall pregnant within one month after being vaccinated with PRIORIX. During this time, you should use an effective method of birth control to avoid pregnancy.

PRIORIX contains lactose, mannitol and sorbitol:

Patients who are intolerant to lactose should note that PRIORIX contains a small amount of lactose. If you have been told by your doctor that your child has intolerance to some sugars, contact your doctor before your child is given PRIORIX.

Patients with rare hereditary conditions of sorbitol intolerance should not be given PRIORIX.

PRIORIX contains traces of neomycin. Tell your doctor if your child has had an allergic reaction to this antibiotic.

3. HOW TO TAKE PRIORIX:

You will not be expected to give yourself PRIORIX. It will be given to you by a person who is qualified to do so.

Your doctor or nurse will inject the recommended dose of vaccine. If an additional (booster) dose is necessary, the doctor will tell you.

PRIORIX is usually injected under the skin, however can occasionally be injected into the muscle either in the upper arm or in the outer thigh.

The vaccine must never be injected into a vein.

If receive more PRIORIX than you should:

Since a healthcare provider will administer PRIORIX, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss your appointment PRIORIX:

Since a healthcare provider will administer PRIORIX, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS:

PRIORIX can have side effects.

Not all side effects reported for PRIORIX are included in this leaflet. Should you/your child's general health worsen, or if you/ your child experiences any untoward effects while using PRIORIX, please consult your doctor, pharmacist or other healthcare professional for advice.

Severe allergic reactions may occur. The symptoms include:

- difficulty in breathing or swallowing
- itchy rash of the hands and feet
- swelling of the eyes and face.

Such reactions will usually occur before leaving the doctor's office. However, if your child gets any of these symptoms you should contact a doctor immediately or go to the casualty department at your nearest hospital.

➔ These are all very serious side effects. If you/your child have them, you may have had a serious allergic reaction to PRIORIX. You/your child may need urgent medical attention or hospitalisation.

Frequent side effects include:

- redness at the injection site
- fever greater than or equal to 38 °C (rectal)

- upper respiratory tract infection
- rash
- pain and swelling at the injection site
- fever greater than or equal to 39,5 °C (rectal).

Less frequent side effects include:

- infection of the middle ear
- swollen glands in the neck, armpit or groin
- loss of appetite
- nervousness
- abnormal crying
- not being able to sleep (insomnia)
- discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- bronchitis
- cough
- swollen glands in the cheek
- diarrhoea
- vomiting
- allergic reactions
- seizures with fever.

Other side effects include:

- infection around the brain or spinal cord (meningitis)
- measles-like symptoms
- mumps-like symptoms (including painful swelling of the testicles and swollen glands in the neck)

- bleeding or bruising more easily than normal due to a drop in a type of blood cell called platelets, unusual bleeding or bruising under the skin
- Infection or inflammation of the brain, spinal cord and peripheral nerves resulting in temporary difficulty when walking (unsteadiness) and/or temporary loss of control of bodily movements, inflammation of some nerves, possible with pins and needles or loss of feeling or normal movement (Guillain-Barré syndrome)
- narrowing or blockage of blood vessels. This may include unusual bleeding or bruising under the skin (Henoch Schonlein purpura) or a fever which lasts for more than five days, associated with a rash on the trunk sometimes followed by a peeling of the skin on the hands and fingers, swollen glands in the neck, red eyes, lips, throat and tongue (Kawasaki disease)
- severe condition of the skin that may affect the mouth and other parts of the body
- joint and muscle pains.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PRIORIX.

5. HOW TO STORE PRIORIX:

Store your vaccine in a refrigerator between +2 °C and +8 °C.

THE VACCINE SHOULD NOT BE FROZEN. Discard if it has been frozen.

Store all medicines out of reach of children.

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

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What PRIORIX contains:

After reconstitution, 1 dose (0,5 ml) of vaccine contains:

Live attenuated measles virusa (Schwarz strain): not less than 103,0 CCID50c

Live attenuated mumps virusa (RIT 4385 strain, derived from Jeryl Lynn strain): not less than 103,7 CCID50c

Live attenuated rubella virusb (Wistar RA 27/3 strain): not less than 103,0 CCID50c

^a produced in chick embryo cells

^b produced in human diploid-(MRC-5)-cells

^c Cell Culture Infective Dose 50 %

The other ingredients are amino acids, lactose, mannitol, neomycin sulphate, sorbitol and water for injections.

WHAT PRIORIX LOOKS LIKE AND CONTENTS OF THE PACK:

The vaccine is a whitish to slightly pink coloured cake or powder, which after mixing with the diluent is a clear peach to fuchsia pink coloured solution.

The diluent is a clear, colourless liquid.

Combined lyophilised vaccine in monodose vial and diluent ampoule.

Combined lyophilised vaccine in monodose vial and diluent in pre-filled syringe with 2 separate needles in pack.

HOLDER OF CERTIFICATE OF REGISTRATION:



GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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