PRIORIX TETRA
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

PRIORIX TETRA®

Measles, mumps, rubella and varicella vaccine

Powder and diluent for solution for injection

Read all of this leaflet carefully before PRIORIX TETRA is given.

PRIORIX TETRA is not for self-medication and should be administered only by a healthcare professional.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for your child. Do not pass it on to others.

WHAT PRIORIX TETRA CONTAINS:

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

Live attenuated measles virus[a]	
(Schwarz strain)	not less than $10^{3,0}$ $CCID_{50}$[c]
Live attenuated mumps virus[a]	
(RIT 4385 strain derived from Jeryl Lynn strain)	not less than $10^{4,4}$ $CCID_{50}$[c]
Live attenuated rubella virus[b]	

(Wistar RA 27/3 strain)	not less than $10^{3,0}$ $CCID_{50}$[c]
Live attenuated varicella virus[b]	
(OKA strain)	not less than $10^{3,3}$ PFU[d]

[a] produced in chick embryo cells

[b] produced in human diploid (MRC-5) cells

[c] $CCID_{50}$ = Cell Culture Infective Dose 50 %

[d] PFU = Plaque Forming Units

The other ingredients are:

Powder: amino acids for injection, lactose, mannitol, sorbitol.

Diluent: water for injections.

Residues: Traces of neomycin sulphate.

WHAT PRIORIX TETRA IS USED FOR:

PRIORIX TETRA is a vaccine for use in children from 9 months up to and including 12 years of age to protect them against illnesses caused by measles, mumps, rubella and varicella (chickenpox) viruses.

When a person is vaccinated with PRIORIX TETRA, the immune system (the body's natural defence system) will make antibodies to protect the person from being infected by measles, mumps, rubella and varicella (chickenpox) viruses.

BEFORE YOU USE PRIORIX TETRA:

PRIORIX TETRA should not be given if your child:

- has previously had any allergic reaction to PRIORIX TETRA, neomycin (an antibiotic) or any component contained in this vaccine. The active substances and other ingredients in PRIORIX TETRA are listed at the beginning of the leaflet. However, if you had a skin

rash (dermatitis) after treatment with neomycin, you can still be vaccinated with PRIORIX TETRA

- has previously had an allergic reaction to any vaccine against measles, mumps, rubella and varicella
- has any severe illness or takes any medicine that weakens the immune system
- PRIORIX TETRA 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 your child.

Take special care with PRIORIX TETRA if your child:

Your doctor needs to know before your child is given PRIORIX TETRA if he/she:

- has a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first
- has a history of febrile convulsions (fits) or a family history of convulsions. In this case your child should be closely monitored after vaccination as fever may occur 5 to 12 days after vaccination
- has a history or family history of allergies
- if your child has ever had a severe allergic reaction to eggs or anything that contained eggs
- has had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual
- has had a blood or plasma transfusion, or human immunoglobulin within the last three months. If so, the antibody response to PRIORIX TETRA may be low so it is usual to wait for three months before giving PRIORIX TETRA

- is due to have a skin test for possible tuberculosis. If this test is done within 6 weeks after receiving PRIORIX TETRA, the result may not be reliable
- is under 12 months old. Children under 12 months may not develop a good immune response 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 you/your child fainted with a previous injection.

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.

The types of viruses that are in PRIORIX TETRA are not usually passed on from the person who has had the vaccine to other people, with the exception of the varicella virus. This may happen when the healthy vaccinee has developed blisters.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional before you are given PRIORIX TETRA.

PRIORIX TETRA must not be administered to pregnant women. It is also important that your daughter does not become pregnant within one month after being vaccinated with PRIORIX TETRA. During this time, your daughter should use an effective method of birth control to avoid pregnancy.

Breastfeeding: There is no information on the use of PRIORIX TETRA during lactation.

Important information about some of the ingredients of PRIORIX TETRA:

Patients who are intolerant to lactose should note that PRIORIX TETRA 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 TETRA.

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

Using other medicines with PRIORIX TETRA:

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

Aspirin or aspirin-type products (also known as salicylates) should not be taken for 6 weeks after vaccination, since we now know that Reye's Syndrome, a rare disease of the brain and liver could occur.

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

HOW TO USE PRIORIX TETRA:

PRIORIX TETRA is intended for children from 9 months up to and including 12 years of age.

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

PRIORIX TETRA is usually injected under the skin or into the muscle, either in the upper arm or in the outer thigh.

Your doctor may wipe the skin with alcohol or other disinfecting agents and will let the skin dry before the injection.

POSIBBLE SIDE EFFECTS:

PRIORIX TETRA can cause side effects, although not everybody gets them.

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

Severe allergic reactions may occur. The symptoms include:

- 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.

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

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

Frequent side effects include:

- local pain
- local redness
- fever greater than 37,5 °C*
- local swelling
- fever greater than 39 °C*
- irritability
- rash (spots and/or blisters).

Less frequent side effects include:

- upper respiratory tract infection
- crying
- generally feeling unwell
- swollen glands in the cheek
- diarrhoea
- vomiting
- loss of appetite
- inability to sleep
- fatigue
- lack of energy
- nervousness
- runny nose
- swollen glands in the neck, armpit and groin
- bronchitis
- infection of the middle ear
- coughing
- seizures with fever
- seizures with fever.

* 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.

Other side effects that may occur include:

- infection around the brain or spinal cord (meningitis)
- shingles (herpes zoster)
- measles-like symptoms
- mumps-like symptoms (including transient, painful swelling of the testicles and swollen glands in the neck)
- infection or inflammation of the brain or spinal cord and peripheral nerves resulting in temporary difficulty when walking (unsteadiness) and/or temporary loss of control of bodily movements, stroke, inflammation of some nerves, possibly 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, red eyes, lips, throat and tongue (Kawasaki disease)
- 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
- severe condition of the skin that may affect the mouth and other parts of the body
- chicken pox-like rash
- joint and muscle pains.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORING AND DISPOSING OF PRIORIX TETRA:

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

Do not freeze.

Store in the original package in order to protect from light.

Store all medicines out of sight of children.

Do not use PRIORIX TETRA after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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

PRESENTATION OF PRIORIX TETRA:

Powder in a vial (Type 1 glass) with a grey stopper and natural aluminium flip-off cap.

Diluent:

0,5 ml of solution in an ampoule (Type 1 glass). Pack sizes of 1, 10 or 100.

or

0,5 ml of solution in a pre-filled syringe (Type 1 glass) with rubber stopper. Pack sizes of 1 or 10 with 2 separate needles. Pack sizes of 1, 10, 20 or 50 without needles.

IDENTIFICATION OF PRIORIX TETRA:

Powder: whitish to slightly pink coloured cake or powder contained in a glass vial sealed with a rubber stopper.

Diluent: clear and colourless liquid, contained in an ampoule, pre-filled syringe with rubber stopper or a vial with a stopper.

REGISTRATION NUMBER:

43/30.1/0127

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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