Package leaflet: Information for the user

Priorix-Tetra powder and solvent for solution for injection in pre-filled syringe
Measles, mumps, rubella and varicella vaccine (live)

Read all of this leaflet carefully before you or your child receive this vaccine because it contains important information for you.
- 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 you or your child only. Do not pass it on to others.
- If you or your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

This leaflet has been written assuming the person receiving the vaccine is reading it, but it can be given to adults and children so you may be reading it for your child.

What is in this leaflet

1. What Priorix -Tetra is and what it is used for

Priorix-Tetra is a vaccine for use in individuals from 11 months of age to protect them against illnesses caused by measles, mumps, rubella and chickenpox (varicella) viruses. In some circumstances, Priorix-Tetra can also be given to children as from 9 months of age.

How Priorix-Tetra works
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 chickenpox (varicella) viruses.

Although Priorix-Tetra contains live viruses, they are too weak to cause measles, mumps, rubella, or chickenpox (varicella) in healthy people.

As with all vaccines, Priorix-Tetra may not fully protect all people who are vaccinated.

2. What you need to know before you receive Priorix-Tetra

Priorix-Tetra should not be given:

- if you are allergic against any of the components of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue,
- if you have previously had an allergic reaction to any vaccine against measles, mumps, rubella and/or varicella,
- if you are known to be allergic to neomycin (an antibiotic agent). A known contact dermatitis (skin rash when the skin is in direct contact with allergens such as neomycin) should not be a problem but talk to your doctor first,
- if you have a severe infection with 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,

- if you have any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or have recently received or are still taking any medicine that weakens the immune system (except low-dose corticosteroid therapy for asthma or replacement therapy). Whether you receive the vaccine will depend upon the level of your immune defences,
- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.

Warnings and precautions

Talk to your doctor or pharmacist before you receive Priorix-Tetra :

- if you have a personal or family history of convulsions (fits) including febrile convulsions. In this case you must be closely monitored after vaccination as fever may occur in particular 5 to 12 days after vaccination (see also section 4),
- if you have ever had a severe allergic reaction to egg protein,
- if you have had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual (see also section 4),
- if you have weakened immune system (e.g. such as HIV infection) or will be starting a medicine that weakens the immune system. You should be closely monitored as the responses to the vaccines may not be sufficient to ensure a protection against the illness (see section 2 "Priorix-Tetra should not be given").

If you are vaccinated within 72 hours after contact with someone with measles or varicella, Priorix-Tetra will to some extent protect you against the disease.

Once vaccinated, you should attempt to avoid for up to 6 weeks after vaccination, whenever possible, close association with the following individuals:
- individuals with a lowered resistance to diseases,
- pregnant women who either have not had chickenpox or have not been vaccinated against chickenpox.
- newborn infants of mothers who either have not had chickenpox or have not been vaccinated against chickenpox.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you fainted with a previous injection.

Like other vaccines, Priorix-Tetra cannot completely protect you 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.

Other medicines and Priorix-Tetra

Tell your doctor if you are taking, have recently taken or might take any other medicines or have recently received any other vaccine.

Your doctor may delay vaccination for at least 3 months if you have received a blood transfusion or human antibodies (immunoglobulins).

If a tuberculin test is to be performed, it should be done either any time before, simultaneously with, or 6 weeks after vaccination with Priorix-Tetra.

The use of salicylates (a substance present in many medicines used to lower fever and relieve pain) should be avoided for 6 weeks following vaccination with Priorix-Tetra.

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

Pregnancy and breast-feeding
Priorix-Tetra should not be administered to pregnant women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

Driving and using machines
There is no information to suggest that Priorix-Tetra affects the ability to drive and use machines.

Priorix-Tetra contains sorbitol, para-aminobenzoic acid, phenylalanine, sodium and potassium
This vaccine contains 14 mg of sorbitol per dose.
Priorix-Tetra contains para-aminobenzoic acid. It may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.
This vaccine contains 583 micrograms of phenylalanine per dose. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
The vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
The vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.

3. How Priorix-Tetra is given

Priorix-Tetra is injected under the skin or into the muscle either in the upper arm or in the outer thigh.

Priorix-Tetra is intended for individuals from 11 months of age. The appropriate time and number of injections that will be given to you will be determined by your doctor on the basis of appropriate official recommendations.

The vaccine should never be given into a vein.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

The following side effects may happen with this vaccine:

- Very common (these may occur with more than 1 in 10 doses of vaccine):
  - pain and redness at the injection site
  - fever of 38°C or higher*
  - swelling at the injection site in adolescents and adults

- Common (these may occur with up to 1 in 10 doses of vaccine):
  - swelling at the injection site in children
  - fever higher than 39.5°C*
  - irritability
  - rash (spots and/or blisters)

- Uncommon (these may occur with up to 1 in 100 doses of vaccine):
  - unusual crying, nervousness, inability to sleep

- generally feeling unwell, lethargy, fatigue
- swollen parotid glands (glands in the cheek)
- diarrhoea, vomiting
- loss of appetite
- upper respiratory tract infection
- rhinitis
- swollen lymph glands

♦ Rare (these may occur with up to 1 in 1 000 doses of vaccine):
- infection of the middle ear
- febrile convulsions
- cough
- bronchitis

* 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.

The following side effects have been reported on a few occasions during routine use of GlaxoSmithKline Biologicals' measles, mumps, rubella or varicella vaccines:

- infection or inflammation of the brain (encephalitis) has been observed following vaccination with live attenuated measles, mumps, rubella and varicella vaccines. In a few cases, this condition has been fatal, especially in people with weakened immune systems (as noted in section 2, Priorix-Tetra must not be used in patients with weakened immune systems). Seek immediate medical attention if you or your child develop loss or reduced levels of consciousness, convulsions or loss of control of bodily movements, accompanied by fever and headache, as these might be a sign of infection or inflammation of the brain. Inform your doctor or pharmacist that you or your child received Priorix-Tetra
- infection or inflammation of the 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)
- joint and muscle pain
- allergic reactions. 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 may occur before leaving the doctor's surgery. However, if you get any of these symptoms you should contact a doctor urgently.
- narrowing or blockage of blood vessels
- punctual or small spotted bleeding or bruising more easily than normal due to a drop in platelets
- erythema multiforme (symptoms are red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body)
- chickenpox-like rash
- shingles (herpes zoster)
- measles and mumps like symptoms (including transient, painful swelling of the testicles and swollen glands in the neck)

Reporting of side effects

If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Priorix-Tetra

Keep this vaccine out of the sight and reach of children.

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

Store and transport refrigerated (2°C - 8°C).

Do not freeze.

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

After reconstitution, the vaccine should be administered promptly or kept in the refrigerator (2°C – 8°C). If it is not used within 24 hours, it should be discarded.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Priorix-Tetra contains

The active substances are: measles, mumps, rubella and varicella live attenuated viruses.

The other ingredients are:
Powder: amino acids (containing phenylalanine), lactose anhydrous, mannitol (E 421), sorbitol (E 420), medium 199 (containing phenylalanine, para-aminobenzoic acid, sodium and potassium).
Solvent: water for injections.

What Priorix-Tetra looks like and contents of the pack

Priorix-Tetra is presented as a powder and solvent for solution for injection (powder in a vial for 1 dose and solvent in a pre-filled syringe (0.5 ml)) with or without separate needles in the following pack sizes:
- with 2 separate needles: pack sizes of 1 or 10.
- without needles: pack sizes of 1 or 10.

Priorix-Tetra is supplied as a whitish to slightly pink coloured powder cake, a portion of which may be yellowish, and a clear colourless solvent (water for injections) for reconstituting the vaccine.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24

Manufacturer

GlaxoSmithKline Biologicals s.a., Rue de l' Institut 89, B-1330 Rixensart, Belgium

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Detailed information on this medicine is available on the web site of: Health Products Regulatory Authority (HPRA)

The following information is intended for healthcare professionals only:

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.

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.

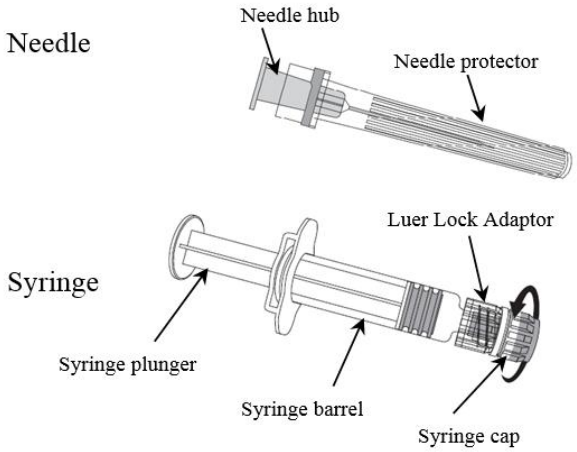
Priorix-Tetra should under no circumstances be administered intravascularly or intradermally.

In the absence of compatibility studies, the medicinal product must not be mixed with other medicinal products.

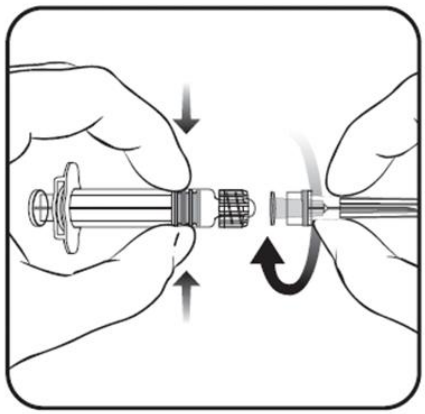
The reconstituted (dissolved) vaccine should be inspected visually. Its colour may vary from clear peach to fuchsia pink due to minor variations of its pH. It **may contain translucent product-related particulates**. This is normal and does not impair the performance of the vaccine.

Do not administer if the vaccine presents other colouration or contains other particulate matter.

The vaccine is reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder.
To attach the needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with Priorix-Tetra might be slightly different (without screw thread) than the syringe illustrated.
In that case, the needle should be attached without screwing.



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).
Whether the LLA is rotating or not, please follow the below steps:

2. Attach the 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 solvent to the powder. The mixture should be well shaken until the powder is completely dissolved in the solvent.

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 the injection needle by repeating step 2 above.

After reconstitution, the vaccine should be administered promptly or kept in the refrigerator (2°C – 8°C). If it is not used within 24 hours, it should be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.