Reason for Update: Type II GDS 11
Agency Approval Date:
Text Date: 09/07/2015
PIL Issue 3 Draft 1
SPC Issue 3 Draft 1

Package leaflet: Information for the user

Priorix-Tetra, powder and solvent for solution for injection

Measles, mumps, rubella and varicella vaccine (live)

Read all of this leaflet carefully before your child receives 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 your child only. Do not pass it on to others.
- If 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.

What is in this leaflet

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

Priorix-Tetra is a vaccine for use in children from 11 months up to and including 12 years 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 your child receives Priorix-Tetra

Priorix-Tetra should not be given

- if your child is 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 your child has previously had an allergic reaction to any vaccine against measles, mumps, rubella and/or varicella;
- if your child is 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 your child has 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 your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether your child receives the vaccine will depend upon the level of your immune defences.
- if your child is pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.

Warnings and precautions

Talk to your doctor or pharmacist before your child receives Priorix-Tetra if :

- your child has a personal or family history of convulsions (fits) including febrile convulsions. In this case your child must be closely monitored after vaccination as fever may occur in particular 5 to 12 days after vaccination (see also section 4);
- your child has ever had a severe allergic reaction to egg protein;
- your child has 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);
- your child has weakened immune system (e.g. such as HIV infection). Your child 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 your child is vaccinated within 72 hours after contact with someone with measles or varicella, Priorix-Tetra will to some extent protect your child against the disease.

Once vaccinated, your child 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 your child fainted with a previous injection.

Like other vaccines, 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.

Other medicines and Priorix Tetra

Tell your doctor if your child is taking, has recently taken or might take any other medicines or has recently received any other vaccine.

Your doctor may delay vaccination for at least 3 months if your child has 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 diphtheria, tetanus, acellular pertussis (whooping cough), *Haemophilus influenzae* type b, inactivated polio (infantile paralysis) and hepatitis B vaccines. The injections should be given at separate injection sites.

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

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

Priorix-Tetra contains sorbitol.
If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before your child receives this vaccine.

3. How Priorix Tetra is given

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

Priorix-Tetra is intended for children from 11 months up to and including 12 years of age. The appropriate time and number of injections that will be given to your child 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*

- Common (these may occur with up to 1 in 10 doses of vaccine):
  - swelling at the injection site
  - 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 occasion during routine use of GlaxoSmithKline Biologicals' measles, mumps, rubella or varicella vaccines:

- 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.
- 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, 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
- punctual or small spotted bleeding or bruising more easily than normal due to a drop in platelets
- erythemamultiforme (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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail:medsafety@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 your child no longer uses. These measures will help protect the environment.

6. Contents of the pack and other information

What Priorix-Tetra contains

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

- The other ingredients are:
  Powder: amino acids, lactose anhydrous, mannitol, sorbitol, medium 199.
  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 vial (0.5 ml)) - Pack sizes of 1, 10 or 100.

Priorix-Tetra is supplied as a white to slightly pink powder 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

This leaflet was last revised in 07/2015

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 for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, the vaccine should be discarded.

The vaccine is reconstituted by adding the entire contents of the supplied vial of solvent to the vial containing the powder. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the solvent.

The colour of the reconstituted vaccine may vary from clear peach to fuchsia pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine. In the event of other variation being observed, discard the vaccine.

A new needle should be used to administer the vaccine.

Withdraw the entire contents of the vial.

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.