

Package leaflet: Information for the user
Priorix, powder and solvent for solution for injection in a pre-filled syringe
Measles, Mumps and Rubella vaccine (live)

Read all of this leaflet carefully before you 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 only. Do not pass it on to others.
- If you get 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 is and what it is used for
2. What you need to know before you receive Priorix
3. How Priorix is given
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 in children from 9 months up, adolescents and adults to protect them against illnesses caused by measles, mumps and rubella viruses.

How Priorix works

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

Although Priorix contains live viruses, they are too weak to cause measles, mumps or rubella in healthy people.

2. What you need to know before you receive Priorix

Priorix 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,
- 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,
- you have 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,
- 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,

- 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 if:

- you have disorders of the central nervous system, a history of convulsion accompanying high fever or family history of convulsions. In case of high fever following vaccination please consult your doctor promptly,
- you have ever had a severe allergic reaction to egg protein,
- you have had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual (see section 4),
- 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 should not be given if”).

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.

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

Children below 12 months of age

Children vaccinated in their first year of life may not be fully protected. Your doctor will advise if additional doses of vaccine are needed.

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

Other medicines and Priorix

Tell your doctor if you are taking, have recently taken or might take any other medicines (or other vaccines).

Priorix may be given at the same time you receive other vaccines such as diphtheria, tetanus, pertussis (acellular), *Haemophilus influenzae* type b, oral or inactivated polio, hepatitis A, hepatitis B, varicella, meningococcal serogroup B vaccines as well as meningococcal serogroup C, meningococcal serogroups A, C, W-135 and Y and pneumococcal conjugate vaccines. Talk to your doctor or nurse for further information.

A different injection site will be used for each vaccine.

If not given at the same time, an interval of at least one month is recommended between administration of Priorix and other live attenuated vaccines.

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.

Pregnancy, breast-feeding and fertility

Priorix 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.

Priorix contains sorbitol, para-aminobenzoic acid, phenylalanine, polysorbate 80, proline, sodium and potassium

This vaccine contains 9 mg of sorbitol per dose.

This vaccine contains para-aminobenzoic acid. It may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

This vaccine contains 334 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.

This vaccine contains 0.65 micrograms of polysorbate 80 per dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

This vaccine contains 407 micrograms of proline per dose. Proline may be harmful for patients with hyperprolinaemia, a rare genetic disorder in which proline builds up in the body. If you have hyperprolinaemia, do not use this medicine unless your doctor has recommended it.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.

3. How Priorix is given

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

Priorix is intended for children from 9 months up, adolescents and adults.

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.

Side effects that occurred during clinical trials with Priorix were as follows:

Very common (may occur with more than 1 in 10 doses of the vaccine): redness at the injection site; fever of 38°C or higher

Common (may occur with up to 1 in 10 doses of the vaccine): pain and swelling at the injection site; fever higher than 39.5 °C; rash (spots); upper respiratory tract infection

Uncommon (may occur with up to 1 in 100 doses of the vaccine): infection of the middle ear; swollen lymph glands (glands in the neck, armpit or groin); loss of appetite; nervousness; abnormal crying; inability to sleep (insomnia); redness, irritation and watering of the eyes (conjunctivitis); bronchitis; cough; swollen parotid glands (glands in the cheek); diarrhoea; vomiting

Rare (may occur with up to 1 in 1,000 doses of the vaccine): convulsions accompanying high fever; allergic reactions

After the marketing of Priorix, the following side effects have been reported on a few occasions:

- joint and muscle pain
- punctual or small spotted bleeding or bruising more easily than normal due to a drop in platelets
- sudden life-threatening allergic reaction

- 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, possibly with pins and needles or loss of feeling or normal movement (Guillain-Barré syndrome)
- narrowing or blockage of blood vessels
- 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)
- 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 HPRC 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

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 after EXP.

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

Do not freeze.

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

After reconstitution, use the vaccine promptly. If this is not possible, it must be stored in the refrigerator (2°C – 8°C) and used within 8 hours of reconstitution.

Do not throw away 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 contains

The active substances are:

After reconstitution, 1 dose (0.5 mL) contains:

Live attenuated measles virus¹ (Schwarz strain) not less than 10^{3.0} CCID₅₀³

Live attenuated mumps virus¹ (RIT 4385 strain, derived from Jeryl Lynn strain)

not less than 10^{3.7} CCID₅₀³

Live attenuated rubella virus² (Wistar RA 27/3 strain)

not less than 10^{3.0} CCID₅₀³

¹ produced in chick embryo cells; ² produced in human diploid (MRC-5) cells; ³ Cell Culture Infective Dose 50 %

The other ingredients are:

Powder: amino acids (containing phenylalanine and proline), lactose (anhydrous), mannitol (E 421), sorbitol (E 420), medium 199 (containing phenylalanine, para-aminobenzoic acid, polysorbate 80 (E 433), proline, sodium and potassium).

Solvent: water for injections

See section 2 “Priorix contains sorbitol, para-aminobenzoic acid, phenylalanine, polysorbate 80, proline, sodium and potassium”.

What Priorix looks like and contents of the pack

Powder and solvent for solution for injection in a pre-filled syringe. The powder is a whitish to slightly pink coloured cake, a portion of which may be yellowish to slightly orange. The solvent is a clear and colourless solution.

Priorix consists of:

- Powder for 1 dose in a glass vial
- Solvent for 1 dose in a pre-filled syringe

Pack sizes of 1 or 10, with 2 separate needles or without needles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Limited
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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 should under no circumstances be administered intravascularly.

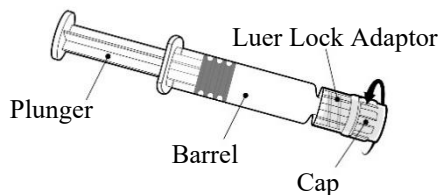
In the absence of compatibility studies, the medicinal product must not be mixed with other medicinal products.

The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to reconstitution or administration. In the event of either being observed, do not use the solvent or the reconstituted vaccine.

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

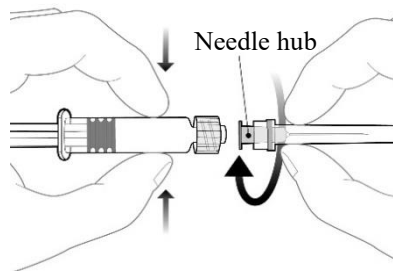
The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder using a suitable needle (21G to 25G).

To attach the needle to the syringe, carefully read the instructions.



Hold the syringe by the barrel, not by the plunger or by the Luer Lock Adaptor (LLA).

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, gently connect the hub to the LLA and rotate a quarter turn clockwise until you feel it lock.

Maintain the needle in the axis of the syringe. 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. Reconstitute the vaccine as described below.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

1. Add the solvent to the powder. Shake well until the powder is completely dissolved in the solvent.
2. Withdraw the entire contents of the vial and administer it.
3. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the injection needle by repeating steps above.

After reconstitution, use the vaccine promptly. If this is not possible, it must be stored in the refrigerator (2°C – 8°C) and used within 8 hours of reconstitution.

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