PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed according to a physician's prescription only

Priorix

Powder and solvent for preparation of a solution for injection

Each dose (0.5 ml) contains:

NLT $10^{3.0}$ $CCID_{50}$ – Live attenuated measles virus

NLT $10^{3.7}$ $CCID_{50}$ – Live attenuated mumps virus

NLT $10^{3.0}$ $CCID_{50}$ – Live attenuated rubella virus

For a list of the inactive and allergenic ingredients in the preparation, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Active immunisation of children from the age of 9 months or older, adolescents and adults against measles, mumps and rubella.

Therapeutic group: viral vaccines.

How does the vaccine work?

When a person is vaccinated with Priorix, the immune system (the body's natural defense 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. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to one of the active ingredients or to any of the additional ingredients contained in the medicine (listed in section 6 "Additional information"). 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 physician 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 physician first.
- you have any illness that weakens the immune system (such as Human Immunodeficiency Virus [HIV] or Acquired Immunodeficiency Syndrome [AIDS]) or if you 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 defenses.
- you are pregnant. In addition, pregnancy should be avoided for one month following vaccination.

Special warnings regarding use of the medicine

Talk to your physician before you receive Priorix if:

- you have disorders of the central nervous system, a history of convulsions accompanying high fever or family history of convulsions. In case of high fever following vaccination, please consult the physician 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 “Side effects”).
- 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 protection against the illness (see section 2 “Do not use the medicine if”).

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore, tell the physician 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. The physician will advise if additional doses of vaccine are needed.

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

Drug interactions

If you are taking, or have recently taken other medicines or other vaccines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

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 serogroup A, C, W-135 and Y and pneumococcal-conjugate vaccines. Talk to your physician 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 physician may delay vaccination for at least three 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 and breast-feeding
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 physician 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.

Important information about some of the ingredients of the medicine
Priorix contains sorbitol, para-aminobenzoic acid, phenylalanine, sodium and potassium.
The preparation contains 9 mg of sorbitol per dose.
Priorix contains para-aminobenzoic acid which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.
The preparation 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.
The preparation contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
The preparation contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the physician only.
Priorix is injected under the skin or into the muscle, either in the upper arm or in the outer thigh.
The vaccine should never be given into a vein.
The appropriate time and number of injections that will be given will be determined by your physician on the basis of appropriate official recommendations.
Do not exceed the recommended dose.

Adhere to the treatment regimen as recommended by the physician.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Priorix may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Side effects that occurred during clinical trials with Priorix were as follows:

Very common side effects

These may occur in **more than 1 in 10** people:

- redness at the injection site
- fever of 38°C or higher.

Common side effects

These may occur in **up to 1 in 10** people:

- pain and swelling at the injection site
- fever higher than 39.5°C
- rash (spots)
- upper respiratory tract infection.

Uncommon side effects

These may occur in **up to 1 in 100** people:

- 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 side effects

These may occur in **up to 1 in 1,000** people:

- 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).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, should be stored in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (between 2°C and 8°C).
- Do not freeze.
- Store in the original package in order to protect from light.
- After reconstitution, the vaccine should be administered promptly. If this is not possible, it must be stored in the refrigerator (between 2°C and 8°C) and used within 8 hours of reconstitution.
- Do not throw away 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. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:

Powder:

Lactose (anhydrous), amino acids (containing phenylalanine), sorbitol, mannitol, medium 199 (containing phenylalanine, para-aminobenzoic acid, sodium and potassium).

Solvent:

Water for injection.

Traces of:

Neomycin sulphate.

- What the medicine looks like and contents of the package:
  Priorix is presented as a powder and solvent for solution for injection (powder in a vial for one dose and solvent in an ampoule or prefilled syringe [0.5 ml]).
  The powder is whitish to slightly pink coloured and the solvent is clear and colourless (water for injection).
- Package sizes of 10 and 100 doses. Needles may be included in the package.
  Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Medicines Registry of the Ministry of Health: 112-06-29388

Revised in November 2025.

Priorix PT v3B 29103

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.

Solvent in ampoule

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

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.

Withdraw the entire contents of the vial.

A new needle should be used to administer the vaccine.

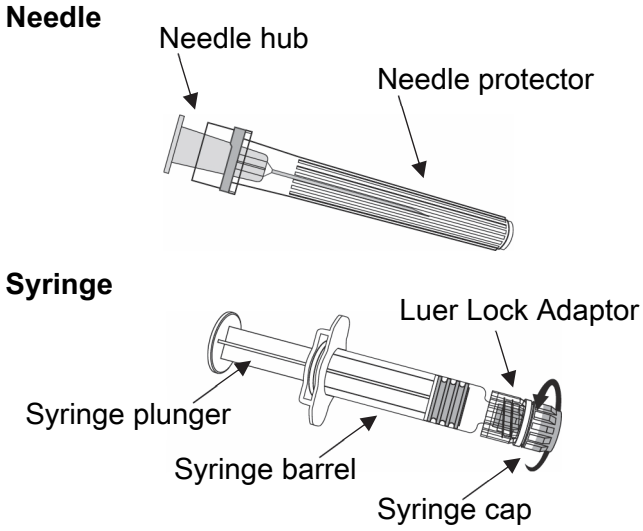
After reconstitution, the vaccine should be administered promptly. If this is not possible, it must be stored in the refrigerator (2°C-8°C) and used within 8 hours of reconstitution.

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

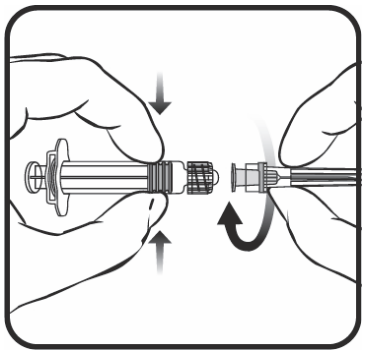
Solvent in pre-filled syringe

The vaccine must be 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 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.

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.

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. 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.