

VACCINATION CONSENT FORM

Priorix®

Powder and solvent for production of a suspension for injection

Measles, mumps and rubella vaccine (live)

Please answer the following questions:

(⊗ Mark with a cross where applicable)

Speak to your vaccinator if you have any further questions about this vaccination.

Please bring any existing vaccination documentation (vaccination card or certificate) with you to your scheduled immunization appointment.

	Yes	No
Is your child suffering from an acute illness or has he/she had an acute illness within the past 7 days (e.g. fever, cough, runny nose, sore throat, or other)? If yes, which illness?	<input type="checkbox"/>	<input type="checkbox"/>
Does your child have an allergy (especially to egg white, medicines)? If yes, to what?.....	<input type="checkbox"/>	<input type="checkbox"/>
Does your child take any medication regularly (e.g. cortisone, cytostatics or blood thinning agents)? If yes, which one(s)?	<input type="checkbox"/>	<input type="checkbox"/>
Is your child suffering from any severe or chronic illness ? (e.g. an inherited or acquired immunodeficiency disease, cancer, autoimmune disease, blood clotting disorder, chronic inflammation of the brain or spinal cord, epileptic seizures) If yes, which illness?.....	<input type="checkbox"/>	<input type="checkbox"/>
Has your child had problems or side effects after being vaccinated in the past (except for slight local reactions such as reddening, swelling, pain at the injection site or mild fever)?	<input type="checkbox"/>	<input type="checkbox"/>
Has your child received any other vaccination within the last 4 weeks ? If yes, which one..... and when?	<input type="checkbox"/>	<input type="checkbox"/>
Has your child had a blood transfusion , an injection of immunoglobulin , or received any blood products in the last 3 months ?	<input type="checkbox"/>	<input type="checkbox"/>
Is your child currently undergoing chemotherapy and/or radiotherapy ?	<input type="checkbox"/>	<input type="checkbox"/>
Has your child undergone any invasive procedure recently (e.g. a surgery)?	<input type="checkbox"/>	<input type="checkbox"/>
If the adolescent to be vaccinated should be pregnant , please indicate with a cross!	<input type="checkbox"/>	<input type="checkbox"/>

Please turn over - thank you!

Please fill out in block capitals - thank you

----- Child's last name	----- Child's first name
----- Address	
----- Child's health insurance number	----- Child's birth date: Day/Month/Year
----- Name of health insurance provider (e.g. WGKK)	
----- Name of legal guardian	

I confirm with my signature, that I have read and understood the package leaflet for the above mentioned vaccine. I have taken account of the information given there on vaccine composition, any contraindications against its administration and possible side effects.

The benefits and risks of vaccination were explained to me in sufficient detail and I had the opportunity to clarify any unanswered questions with the vaccinator.

I agree to be vaccinated.

I agree to the transfer of data for invoicing purposes and electronic documentation in a computer program.

Date

Signature of the person being vaccinated or of parent/legal guardian

Underage children (children under the age of 14) require the consent of one parent or the person responsible for the child's upbringing (legal guardian). Adolescents must give their consent themselves provided that they possess reasoning ability and power of judgement.

Information:

- This vaccination is recommended by the Federal Ministry of Health and is provided free of charge within the Austrian vaccination scheme.
- For further information please refer to the vaccination brochure or visit the website of the Federal Ministry of Health at www.bmg.gv.at under "Vaccinations".
- If any side effects occur, please inform your vaccine provider.
- **If you miss a vaccination appointment, please make sure you are given the missed vaccination as soon as possible.**

Doctor's comments:

Date

Doctor's stamp and signature

IMPORTANT NOTES ON THE VACCINE

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Measles, mumps and rubella vaccine (live)

WHAT PRIORIX IS AND WHAT IT IS USED FOR

Priorix is a vaccine used to provide protection to children from 11 months onwards, adolescents and adults against illnesses caused by measles, mumps and rubella viruses. In certain circumstances, Priorix can be given to children from 9 months of age.

A Priorix vaccination causes the immune system (the body's natural defence system) to make antibodies that protect the person from being infected by measles, mumps and rubella viruses.

Priorix contains live viruses. However, they have been weakened (attenuated) to such an extent that they generally cannot cause measles, mumps or rubella in healthy people.

BEFORE PRIORIX IS GIVEN TO YOU OR YOUR CHILD

Priorix should not be given if

- you/your child are/is hypersensitive (allergic) to any of the ingredients in Priorix. Signs of an allergic reaction may include itchy skin rash, breathing problems and swelling of the face or tongue.
- you/your child are/is known to be allergic to neomycin (an antibiotic agent). Known contact dermatitis (skin rash which occurs when the skin is in direct contact with allergens such as neomycin) should not be a problem. However, you should talk to your doctor about it first.
- you/your child have/has an acute severe illness with fever. In such cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem. However, you should talk to your doctor about it first.
- you/your child have/has any illness or take/takes any medicine that weakens the immune system.

Priorix must not be administered to pregnant women. Pregnancy must be avoided for at least three months after vaccination with Priorix.

Please tell your doctor if you/your child are/is infected with the human immunodeficiency (HIV) virus. In this case, your doctor will decide whether the vaccination can be given.

Special care must be taken with Priorix if

- you/your child have/has disorders of the central nervous system, a history of seizures accompanying high fever or family history of seizures. In this case, high body temperatures should be prevented. Please consult your doctor.
- if you/your child have/has ever had a severe allergic reaction to egg white.
- if you or your child have/has had a side effect after vaccination against measles, mumps or rubella that involved bruising more readily or bleeding for longer than usual.

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

Using Priorix with other medicines or vaccines

Please tell your doctor or pharmacist if you/your child are/is taking or have/has recently taken any other medicines, including medicines obtained without a prescription or if you/your child have/has received another vaccine recently.

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

If a tuberculin test is to be performed (skin test for tuberculosis), it should be performed either any time before, at the same time as, or 6 weeks after vaccination with Priorix.

Priorix may be administered at the same time as other recommended vaccines. The injections should be given at separate body sites. Your doctor will advise you accordingly.

POSSIBLE SIDE EFFECTS

Like all medicines, Priorix can cause side effects, although these do not affect everybody.

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

Very common (affects more than 1 out of 10 people):

- redness at the injection site
- fever (38°C and higher)

Common (affects 1 to 10 out of 100 people):

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

Uncommon (affects 1 to 10 out of 1,000 people):

- infection of the middle ear
- swollen lymph glands (glands in the neck, armpit or groin)
- loss of appetite
- nervousness
- abnormal crying
- sleeplessness
- redness, irritation and watering of the eyes (conjunctivitis)
- bronchitis
- cough
- swollen parotid glands (glands in the cheek)
- diarrhoea
- vomiting

Rare (affects 1 to 10 out of 10,000 people)

- febrile seizures
- allergic reactions

During post-marketing surveillance of Priorix, the following additional side effects were reported occasionally:

- joint pain and inflammation
- dot-shaped or small-spotted bleeding or bruising more easily than normal due to a drop in blood platelets
- sudden life-threatening allergic reactions
- inflammation of the meninges, brain, spinal cord and peripheral nerves, Guillain Barré syndrome (ascending paralysis up to respiratory paralysis)

- Kawasaki syndrome (major signs of the illness are for instance: fever, skin rash, swollen lymph glands, inflammation and rash of the mucous membranes of the mouth and throat)
- erythema multiforme (symptoms include 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)

In rare cases, you/your child may experience mumps-like or measles-like symptoms.
In isolated cases, transient, painful swelling of the testicles has been reported.