

PRIORIX

Measles-Mumps-Rubella vaccine live

CONSUMER MEDICINE INFORMATION

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about PRIORIX vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you or your child having PRIORIX against the expected benefits.

If you have any concerns about PRIORIX talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again.

WHAT PRIORIX IS USED FOR

PRIORIX is a vaccine used to prevent three diseases, measles, mumps and rubella (German measles). The vaccine is sometimes called MMR vaccine.

Measles, mumps and rubella are all infectious diseases caused by viruses. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

Measles

Measles is a highly infectious viral illness. Measles is spread by small droplets from the nose, throat or mouth of an infected person (often before it is obvious they have measles). Measles often begins with

a fever, runny nose, hacking cough and conjunctivitis (eye inflammation). The rash appears 3-5 days after the onset of symptoms and spreads rapidly all over the body. Measles is often a severe disease complicated by ear infection and pneumonia (lung infection). Encephalitis (swelling of the brain) can also occur and can sometimes result in permanent brain damage or death.

Unimmunised children in the following groups are at particular risk from severe measles infection:

- children with chronic conditions such as cystic fibrosis, congenital heart or kidney disease, failure to thrive, Down's Syndrome
- children from the age of 1 year upwards in child care centres, family day care and playgroups
- children living in institutions
- Aboriginal and Torres Strait Islander children.

Mumps

Mumps is an infectious viral disease spread by infected droplets of saliva. Symptoms often begin with chilly sensations, headache, loss of appetite, general unwellness and fever. The salivary glands on one or both sides of the face can then become very painful and swollen. Complications include meningoencephalitis (swelling around the brain) and in older patients the disease may involve other organs e.g. testes in males.

Rubella (German measles)

Rubella is generally a mild infectious viral illness spread by airborne droplets. It can cause mild fever, general unwellness, swollen glands and mild red rash. It often goes unnoticed in adolescents and adults. However rubella can cause miscarriage, stillbirth or birth defects in infants born to mothers infected with rubella during the early months of pregnancy.

Vaccination is the best way to protect against these severe diseases. The vaccine will not protect against diseases caused by other types of viruses or organisms.

BEFORE RECEIVING PRIORIX

DO NOT HAVE PRIORIX IF:

- you have/your child has had an allergic reaction to PRIORIX or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue.
- you have/your child has ever had a severe allergic reaction to eggs or anything that contained eggs. Signs of an allergic reaction are listed above.
- if you have/your child has had PRIORIX or another MMR vaccine before and became unwell, tell your doctor or nurse before the next dose is given.

- you have/your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.
- you are or think you may be pregnant or if you intend to become pregnant within one month. Your doctor will discuss with you the risks of receiving PRIORIX during pregnancy.
- you have/your child has lowered immunity. This can occur in persons:
 - with inherited (or family history of) immune deficiency conditions
 - with abnormal blood conditions or blood protein (immunoglobulin) disorders
 - with cancer
 - receiving or who have received certain drugs (i.e. cyclosporin, corticosteroids, and cancer medicines)
 - receiving or who have received radiation therapy

PRIORIX may generally be given to people with Human Immunodeficiency Virus (HIV) infection.

If needed, you can talk to your doctor about use of PRIORIX in HIV-positive people.

- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering

If you are not sure whether PRIORIX should be given, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you/or your child.

BEFORE HAVING PRIORIX TELL YOUR DOCTOR IF

- you have any medical problems such as:
 - tuberculosis (TB) - PRIORIX may affect the tuberculin skin

test. Tuberculin testing may be done before or at the same time that PRIORIX is given.

- a history or family history of convulsions (fits or seizures)
- a history or family history of allergic diseases
- a skin allergy to neomycin
- a bleeding disorder. Sometimes PRIORIX may need to be given differently in people with bleeding problems.
- a weakened immune system. You/your child should be closely monitored as the response to the vaccine may not be sufficient to ensure protection against the illness.
- you have/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- you are breast feeding. Your doctor will discuss the risks and benefits of vaccination.
- you have received another vaccine within the last month.
- you have/your child has received a blood or plasma transfusion, or been given gamma globulin or other immunoglobulin within the last 3 months. PRIORIX may be less effective if given within 3 months of these products. Your doctor will decide when to give the vaccine.
- you are/your child is taking any prescription or OTC (over-the-counter) medicines. Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if PRIORIX is to be given with another vaccine or medicine.
- you have/ your child has had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you/your child fainted with a previous injection.

HAVING OTHER VACCINES

Tell your doctor or nurse if you or your child has received another vaccine recently.

PRIORIX can be given at the same time as other vaccines.

A different injection site will be used for each vaccine.

HOW PRIORIX IS GIVEN

The doctor or nurse will give PRIORIX as an injection.

If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

HOW MUCH IS GIVEN

PRIORIX is generally given as a single 0.5 mL dose. The same dose is used for children and adults.

HOW IT IS GIVEN

The vaccine comes as a powder which is mixed with sterile water before use. PRIORIX is injected under the skin (subcutaneously) or into muscle, either in the upper arm or in the outer thigh. PRIORIX is generally injected into the upper leg muscle in infants under 12 months of age. In children over 12 months of age and older children and adults the injection may be given in the upper arm muscle.

PRIORIX should never be given into a vein.

WHEN IT WILL BE GIVEN

The first dose of PRIORIX is generally given to children at 12 months of age. A second dose is then administered to children at 4-6

years of age; preferably before commencement at school.

IF A DOSE IS MISSED

If your child misses a scheduled dose, talk to your doctor or nurse and arrange another visit as soon as possible.

AFTER RECEIVING PRIORIX

THINGS YOU MUST NOT DO:

- do not become pregnant for one month after receiving PRIORIX vaccination. Talk to your doctor as soon as possible, if you do become pregnant within this time.

THINGS YOU MUST DO:

Tell your doctor you/your child has received PRIORIX if:

- you/they are to have a tuberculin skin test for tuberculosis within 4-6 weeks after vaccination. The results of the test may be affected by the vaccine.
- you/they are to have another vaccine within 1 month after vaccination.
- you/they are to have a blood or plasma transfusion, or be given gamma globulin or other immunoglobulin within 2 weeks after vaccination.

THINGS TO BE CAREFUL OF:

Be careful driving or operating machinery until you know how PRIORIX affects you. PRIORIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or lightheadedness. Make sure you know how you react to PRIORIX before you drive a car or operate machinery, or do anything that could

be dangerous if you are dizzy or lightheaded.

It is advised to remain in the clinic for about 15 minutes after receiving the injection. There is a risk of allergic reactions. These may be local or widespread 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. These reactions will usually occur before leaving the doctor's surgery. If these symptoms occur, you should contact a doctor immediately.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you (or your child) have troublesome symptoms after having had a dose of PRIORIX.

PRIORIX helps protect most people from measles, mumps and rubella infection, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment. The chance of your child having a serious side effect is very much less than the chance of you or your child having a permanent injury from the natural infections.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with PRIORIX are mild. These effects, as with other vaccines, generally occur around the injection site.

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

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- pain and redness at the injection site

- fever greater than or equal to 38°C (rectal)

Common (these may occur with up to 1 in 10 doses of the vaccine):

- swelling at the injection site
- fever greater than 39.5°C (rectal)
- rash (spots and/or blisters)
- upper respiratory tract infection
- infection of the middle ear
- viral infection
- nervousness
- bronchitis
- cough
- runny nose
- diarrhoea
- vomiting
- headache
- sore throat and discomfort when swallowing

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- allergic reactions
- tiredness (fatigue)
- swelling of the mouth and throat
- toothache
- loss of appetite
- nausea
- abnormal crying
- not being able to sleep (insomnia)
- discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- swollen glands in the cheek
- swollen glands in the neck, armpit or groin
- itchiness
- cold sores, shingles
- feeling generally unwell, dizziness, tiredness
- harsh breathing sounds
- pneumonia
- nose bleeds
- stomach pain or discomfort
- dizziness

Rare (these may occur with up to 1 in 1,000 doses of the vaccine):

- seizures with fever

After commercialisation, the following additional side effects have been rarely reported in people vaccinated with PRIORIX:

- mumps like symptoms (including transient, painful swelling of the testicles and swollen glands in the neck)
- temporary lumpy rash that may affect the skin, mouth and other parts of the body
- bleeding or bruising more easily than normal which may be associated with skin rashes/peeling or fever
- joint and muscle pains
- infection around the brain or spinal cord (meningitis)
- infection or inflammation of the nervous system resulting in temporary loss of control of bodily movements, walking or sensation changes

Other side effects not listed above, can also occur during or soon after a dose of PRIORIX.

Check with your doctor or nurse if you or your child has any other effects.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

STORAGE

PRIORIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store PRIORIX always:

- Keep PRIORIX in the refrigerator stored between 2°C and 8°C. DO NOT STORE PRIORIX IN THE FREEZER. Do not store it in the bathroom, near the sink, or leave it in the car on hot days. Avoid exposing the vaccine to sunlight.
- Keep the vaccine out of the reach of children.

- Keep PRIORIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over PRIORIX that has expired or has not been used.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

PRIORIX comes as a whitish to slightly pink powder in a glass vial. This is mixed (reconstituted) with water diluent supplied in a prefilled syringe. The reconstituted vaccine may vary in colour from clear peach to fuchsia pink.

The vaccine should be injected as soon as possible after reconstitution, and no later than 8 hours after reconstitution.

INGREDIENTS

The active ingredients of PRIORIX are live weakened measles, mumps and rubella viruses in a dry powder. Each 0.5 mL dose contains not less than:

- $10^{3.0}$ CCID₅₀ (cell culture infectious dose 50%) of the Schwarz measles
- $10^{3.7}$ CCID₅₀ of the RIT 4385 mumps, and
- $10^{3.0}$ CCID₅₀ of the Wistar RA 27/3 rubella virus strains.

The inactive ingredients in the vaccine are: lactose, amino acids, sorbitol and mannitol. Neomycin sulphate is present as a residual from the manufacturing process. The vaccine is mixed with sterile Water for Injection before use.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

FURTHER INFORMATION

PRIORIX is only available if prescribed by a doctor.

PRIORIX comes as a single or 10 dose packs containing a whitish to slightly pink powder in a glass vial and the diluent in a prefilled syringe (AUST R 97842).

MANUFACTURER

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