

VACCINE INFORMATION STATEMENT

MMRV Vaccine

What You Need to Know

(Measles, Mumps, Rubella and Varicella)

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Measles, Mumps, Rubella and Varicella

Measles, Mumps, Rubella, and Varicella (chickenpox) can be serious diseases:

Measles

- Causes rash, cough, runny nose, eye irritation, fever.
- Can lead to ear infection, pneumonia, seizures, brain damage, and death.

Mumps

- Causes fever, headache, swollen glands.
- Can lead to deafness, meningitis (infection of the brain and spinal cord covering), infection of the pancreas, painful swelling of the testicles or ovaries, and, rarely, death.

Rubella (German Measles)

- Causes rash and mild fever; and can cause arthritis, (mostly in women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

Varicella (Chickenpox)

- Causes rash, itching, fever, tiredness.
- Can lead to severe skin infection, scars, pneumonia, brain damage, or death.
- Can re-emerge years later as a painful rash called shingles.

These diseases can spread from person to person through the air. Varicella can also be spread through contact with fluid from chickenpox blisters.

Before vaccines, these diseases were very common in the United States.

2 MMRV Vaccine

MMRV vaccine may be given to children from 1 through 12 years of age to protect them from these four diseases.

Two doses of MMRV vaccine are recommended:

- The first dose at **12 through 15 months of age**
- The second dose at **4 through 6 years of age**

These are *recommended* ages. But children can get the second dose up through 12 years as long as it is at least 3 months after the first dose.

Children may also get these vaccines as 2 separate shots: **MMR** (measles, mumps and rubella) and **varicella** vaccines.

1 Shot (MMRV) or 2 Shots (MMR & Varicella)?

- Both options give the same protection.
- One less shot with MMRV.
- Children who got the first dose as MMRV have had more fevers and fever-related seizures (about 1 in 1,250) than children who got the first dose as separate shots of MMR and varicella vaccines on the same day (about 1 in 2,500).

Your doctor can give you more information, including the Vaccine Information Statements for MMR and Varicella vaccines.

Anyone 13 or older who needs protection from these diseases should get MMR and varicella vaccines as separate shots.

MMRV may be given at the same time as other vaccines.

3 Some children should not get MMRV vaccine or should wait

Children should not get MMRV vaccine if they:

- Have ever had a life-threatening allergic reaction to a previous dose of MMRV vaccine, or to either MMR or varicella vaccine.
- Have ever had a life-threatening allergic reaction to any *component* of the vaccine, including gelatin or the antibiotic neomycin. Tell the doctor if your child has any severe allergies.
- Have HIV/AIDS, or another disease that affects the immune system.
- Are being treated with drugs that affect the immune system, including high doses of oral steroids for 2 weeks or longer.
- Have any kind of cancer.
- Are being treated for cancer with radiation or drugs.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Check with your doctor if the child:

- Has a history of seizures, or has a parent, brother or sister with a history of seizures.
- Has a parent, brother or sister with a history of immune system problems.
- Has ever had a low platelet count, or another blood disorder.
- Recently had a transfusion or received other blood products.
- Might be pregnant.

Children who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMRV vaccine. Children who are only mildly ill may usually get the vaccine.

Ask your doctor for more information.

4 What are the risks from MMRV vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMRV vaccine causing serious harm, or death, is extremely small.

Getting MMRV vaccine is much safer than getting measles, mumps, rubella, or chickenpox.

Most children who get MMRV vaccine do not have any problems with it.

Mild problems

- Fever (about 1 child out of 5).
- Mild rash (about 1 child out of 20).
- Swelling of glands in the cheeks or neck (rare).

If these problems happen, it is usually within 5–12 days after the first dose. They happen less often after the second dose.

Moderate problems

- Seizure caused by fever (about 1 child in 1,250 who get MMRV), usually 5–12 days after the first dose. *They happen less often when MMR and varicella vaccines are given at the same visit as separate shots (about 1 child in 2,500 who get these two vaccines), and rarely after a 2nd dose of MMRV.*
- Temporary low platelet count, which can cause a bleeding disorder (about 1 child out of 40,000).

Severe problems (very rare)

Several severe problems have been reported following MMR vaccine, and might also happen after MMRV. These include severe allergic reactions (fewer than 4 per million), and problems such as:

- Deafness.
- Long-term seizures, coma, lowered consciousness.
- Permanent brain damage.

5

What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

6

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

7

How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim) MMRV Vaccine

5/21/2010

42 U.S.C. § 300aa-26

Office Use Only



VACCINE INFORMATION STATEMENT

Tdap Vaccine

(Tetanus, Diphtheria,
and Pertussis)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages.
See www.immunize.org/vis

Hojas de Información Sobre Vacunas están disponibles en Español
y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Tetanus, diphtheria and pertussis can be very serious diseases, even for adolescents and adults. Tdap vaccine can protect us from these diseases.

TETANUS (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected.

DIPHTHERIA can cause a thick coating to form in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

- It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.

Before vaccines, the United States saw as many as 200,000 cases a year of diphtheria and pertussis, and hundreds of cases of tetanus. Since vaccination began, tetanus and diphtheria have dropped by about 99% and pertussis by about 80%.

2 Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did *not* get Tdap at that age should get it as soon as possible.

Tdap is especially important for health care professionals and anyone having close contact with a baby younger than 12 months.

Pregnant women should get a dose of Tdap during *every* pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

A similar vaccine, called Td, protects from tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have not already gotten a dose. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor can give you more information.

Tdap may safely be given at the same time as other vaccines.

3 Some people should not get this vaccine

- If you ever had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis containing vaccine, OR if you have a severe allergy to any part of this vaccine, you should not get Tdap. Tell your doctor if you have any severe allergies.
- If you had a coma, or long or multiple seizures within 7 days after a childhood dose of DTP or DTaP, you should not get Tdap, unless a cause other than the vaccine was found. You can still get Td.
- Talk to your doctor if you:
 - have epilepsy or another nervous system problem,
 - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
 - ever had Guillain-Barré Syndrome (GBS),
 - aren't feeling well on the day the shot is scheduled.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Brief **fainting spells** can follow a vaccination, leading to injuries from falling. Sitting or lying down for about 15 minutes can help prevent these. Tell your doctor if you feel dizzy or light-headed, or have vision changes or ringing in the ears.

Mild problems following Tdap

(Did not interfere with activities)

- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

Moderate problems following Tdap

(Interfered with activities, but did not require medical attention)

- Pain where the shot was given (about 1 in 5 adolescents or 1 in 100 adults)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 3 in 20 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 3 in 100).

Severe problems following Tdap

(Unable to perform usual activities; required medical attention)

- Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

A **severe allergic reaction** could occur after any vaccine (estimated less than 1 in a million doses).

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 or visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim) Tdap Vaccine

05/09/2013

42 U.S.C. § 300aa-26

Office Use
Only



Kimberly Hamada NP

215-584-9542

7506